



Australian Government

Department of Health

SCHEDULE OF PHARMACEUTICAL BENEFITS

This Schedule is also available on the internet at
www.pbs.gov.au

EFFECTIVE

1 May 2015 – 31 May 2015

(ALL PREVIOUS EDITIONS CANCELLED)

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This Schedule provides information on the arrangements for the prescribing and supply of pharmaceutical benefits. These arrangements operate under the *National Health Act 1953*. However, at the time of printing, the relevant legislation giving authority for the changes included in this issue of the Schedule may still be subject to the usual Parliamentary scrutiny. This book is not a legal document, and, in cases of discrepancy, the legislation will be the source document for payment for the supply of pharmaceutical benefits. The legislation is available from the Federal Register of Legislative Instruments website at <http://www.frli.gov.au>.

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CONTENTS

PHARMACEUTICAL BENEFITS..... 6

FEES, PATIENT CONTRIBUTIONS AND SAFETY NET	
THRESHOLDS	6
PREScriBER BAG	7
<i>Deletions</i>	7
Deletion – Item.....	7
GENERAL PHARMACEUTICAL BENEFITS	7
<i>Additions</i>	7
Addition – Item.....	7
Addition – Brand	7
Addition – Equivalence Indicator	7
<i>Deletions</i>	8
Deletion – Item.....	8
Deletion – Brand	8
Deletion – Equivalence Indicator.....	8
<i>Alterations</i>	8
Changes to Restrictions	8
Alteration – Restriction Level	9
Alteration – Manufacturer Code	10
Alteration – Number of Repeats	10
<i>Advance Notices</i>	11
1 June 2015	11
Deletion – Brand	11
1 July 2015.....	11
Deletion – Brand	11
1 August 2015.....	11
Deletion – Brand	11
HIGHLY SPECIALISED DRUGS PROGRAM (PUBLIC HOSPITAL)	11
<i>Alterations</i>	11
Changes to Restrictions	11
<i>Advance Notices</i>	11
1 August 2015.....	11
Deletion – Brand	11
HIGHLY SPECIALISED DRUGS PROGRAM (PRIVATE HOSPITAL)	11
<i>Alterations</i>	11
Changes to Restrictions	11
<i>Advance Notices</i>	11
1 August 2015.....	11
Deletion – Brand	11

ADDRESSES — DEPARTMENT OF HUMAN SERVICES..... 12

AUTHORITY PRESCRIPTION APPLICATIONS 13

REQUESTS FOR DRUGS VIA THE SPECIAL ACCESS SCHEME (SAS) 13

POISONS INFORMATION CENTRES..... 14

DRUG INFORMATION CENTRES 14

LIST OF CONTACT OFFICERS FOR RECALLS OF THERAPEUTIC GOODS 15

INDEX OF MANUFACTURERS' CODES 16

SECTION 1 — EXPLANATORY NOTES 24

INTRODUCTION	24
1. THE SCHEDULE — WHERE TO FIND WHAT	24
<i>Section 1</i>	24
<i>Section 2</i>	24
<i>Section 3</i>	24
<i>Section 4</i>	25
<i>Repatriation Schedule of Pharmaceutical Benefits</i>	25
2. PRESCRIBING MEDICINES — INFORMATION FOR PBS	
PRESCRIBERS.....	25
<i>PBS prescribers</i>	25
<i>PBS Prescription forms</i>	25
PBS stationery order forms.....	26
<i>Preparing general PBS prescriptions</i>	26
Do's and Don't's.....	26
Writing the PBS prescription	26
<i>Restrictions</i>	27
<i>Authority PBS prescriptions</i>	27
Authority required PBS Prescriptions	27
Authority required (STREAMLINED) PBS Prescriptions.....	27
Writing authority PBS prescriptions	28
<i>Maximum quantities and repeats</i>	28
<i>Regulation 24</i>	28
<i>Urgent cases</i>	29
<i>Drugs of addiction</i>	29
<i>Prescriber bag supplies</i>	29
<i>Improving the capacity of the PBS to meet particular Aboriginal and Torres Strait Islander health needs</i>	29
How to prescribe these items?	29
Aboriginal and Torres Strait Islander identification	29
Asking about Aboriginal and/or Torres Strait Islander identification.....	30
Aboriginal and Torres Strait Islander health	30
Communication and cultural issues.....	30
3. SUPPLYING MEDICINES — WHAT PHARMACISTS NEED TO KNOW.....	31
<i>Eligible suppliers</i>	31
Conditions of Approval for approved pharmacists	31
Other requirements for approved pharmacists	32
<i>Before supplying pharmaceutical benefits</i> ..	32

<i>Supplying pharmaceutical benefits</i>	32
Do's and Don'ts	32
What to do if the Schedule changes.....	33
<i>Suspected forgery</i>	33
<i>Regulation 24</i>	33
<i>Repeat authorisations</i>	33
Preparing Repeat Authorisation Forms	33
Repeat authorisations for deferred supply	33
<i>Authority PBS prescriptions</i>	34
<i>Urgent cases</i>	34
<i>Receipts</i>	34
<i>Prescriber bag supplies</i>	34
4. PATIENT CHARGES	34
<i>Type of patient</i>	34
<i>Establishing entitlement</i>	35
<i>What to charge</i>	35
Patient contribution	35
Patient contributions for early supply of some PBS medicines	35
Special patient contributions, brand premiums and therapeutic group premiums	35
Increased quantities	36
Regulation 24	36
After hours	36
Delivery	36
5. THE SAFETY NET SCHEME	36
<i>Safety net thresholds</i>	36
Safety net cross-over arrangements	37
<i>Recording PBS prescriptions</i>	37
<i>Hospital prescription record forms</i>	38
<i>Multi-item prescription forms</i>	38
<i>Qualifying PBS prescriptions</i>	38
<i>Lost prescription record forms</i>	38
<i>Retrospective entitlement and patient refunds</i>	38
<i>Applying for a Safety Net Entitlement/Concession Card</i>	38
<i>Issuing a Safety Net Entitlement/Concession Card</i>	39
<i>Issuing supplementary cards</i>	39
<i>Notification to the Department of Human Services and claim for payment</i>	39
<i>Lost Safety Net Entitlement/Concession Cards</i>	39
<i>Pharmacy record of issued cards</i>	39
6. DEPARTMENT OF HUMAN SERVICES ENTITLEMENT CHECKS	39
General Patients.....	39
Concessional Patients.....	39
<i>Entitlement checking procedures</i>	40
General Patients.....	40
Concessional Patients.....	40
Step by step	40
7. HOW PHARMACISTS CLAIM REIMBURSEMENT: INFORMATION REQUIRED	40
<i>PBS Prescription identification</i>	40
<i>Serial numbers</i>	41
Repeat authorisations for authority PBS prescriptions.....	41
Repeat authorisations for deferred supply.....	41
<i>Dropper containers</i>	41
<i>Extemporaneously-prepared pharmaceutical benefits not listed in the Standard Formulae List</i>	41
PBS prescriptions paid on an average price basis.....	41
Pricing non-pre-priced extemporaneous preparations	41
<i>RPBS prescriptions for items not included in either the PBS or RPBS Schedule</i>	41
<i>Payment to Pharmacists for Dispensing Premium-free Substitutable Medicines</i>	41
8. HOW PHARMACISTS CLAIM REIMBURSEMENT: DOCUMENTS TO BE SUBMITTED	42
<i>Completing the claim form</i>	42
<i>Lodging claims</i>	42
<i>Reconciliation statements</i>	42
9. PRICING PBS PRESCRIPTIONS	42
<i>Pricing principles</i>	42
<i>Pricing dates</i>	43
<i>Pricing ready-prepared items</i>	43
For maximum quantities.....	43
For lesser quantities	43
Wastage table percentage.....	43
<i>Pricing extemporaneously-prepared items</i> .	43
General	43
Pricing of ingredients.....	44
Pricing PBS prescriptions where extra ingredients are added to a formula.....	44
Containers	44
Special provisions for extemporaneous PBS prescriptions outside the Standard Formulae List	44
10. MISCELLANEOUS	45
<i>References</i>	45
<i>Standards</i>	45
<i>Legislation</i>	45
NURSE PRACTITIONER PBS PRESCRIBING	45
MIDWIFE PBS PRESCRIBING.....	46
OPTOMETRIST PBS PRESCRIBING	46
GUIDELINES FOR SHARED CARE OF GLAUCOMA PATIENTS	47
THERAPEUTIC INDEX	48

SECTION 2 – READY-PREPARED

PHARMACEUTICAL BENEFITS..... 53

SYMBOLS USED IN THE SCHEDULE	53
RESTRICTED BENEFITS	53
BRAND EQUIVALENCE	53
BRAND PREMIUM POLICY.....	53
THERAPEUTIC GROUP PREMIUM POLICY	54
PRESCRIBER BAG	55
GENERAL PHARMACEUTICAL BENEFITS	59
PHARMACEUTICAL BENEFITS FOR PALLIATIVE CARE ...	661
ITEMS AVAILABLE UNDER SPECIAL ARRANGEMENTS(SECTION 100)	677

SECTION 3 – CONTAINER PRICES, FEES, STANDARD PACKS AND PRICES FOR READY

PREPARED PHARMACEUTICAL BENEFITS..... 1209

SECTION 4..... 1225

DRUG TARIFF	1226
CONTAINER PRICES	1230
STANDARD FORMULA PREPARATIONS.....	1231
TABLE OF CODES, MAXIMUM QUANTITIES, AND NUMBER OF REPEATS FOR EXTEMPORANEOUSLY PREPARED BENEFITS	1233

REPATRIATION SCHEDULE OF PHARMACEUTICAL BENEFITS 1234

BENEFICIARIES' ENTITLEMENT CARDS AND ELIGIBILITY FOR REPATRIATION	
PHARMACEUTICAL BENEFITS	1235
RPBS EXPLANATORY NOTES.....	1236
<i>Introduction</i>	1236
The Australian Repatriation System	1236
<i>RPBS prescribing provisions</i>	1236
Prior Approval Arrangements.....	1236
Palliative Care Drugs.....	1237
Dental Prescribing	1237
Prescribing by optometrists	1237
<i>Provisions governing pricing and payment for RPBS benefits</i>	1238
Introduction	1238
Pricing of Schedule Items	1238
Pricing of Non-Schedule Ready Prepared Items	1238
Pricing of Non-Schedule Extemporaneously Prepared Items.....	1238
Miscellaneous Pricing Rules	1238
<i>General</i>	1238
Packaging Material, Postage or Freight	1238
Payment for Items Supplied at Short Intervals	1238
Receipts for Patient Charges	1239
Special Patient Contributions	1239

Therapeutic Group Premiums — Authority Processing.....	1239

DEPARTMENT OF VETERANS' AFFAIRS.....1239

SUMMARY OF CHANGES 1240

REPATRIATION PHARMACEUTICAL BENEFITS.....	1240
<i>Additions</i>	1240
Addition – Brand.....	1240
<i>Deletions</i>	1240
Deletion – Brand.....	1240

THERAPEUTIC INDEX FOR RPBS 1241

SECTION 1.....	1243
SECTION 2.....	1288

GENERIC/PROPRIETARY INDEX.....1291

THERAPEUTIC GROUP PREMIUM POLICY 1385

BRAND PREMIUM POLICY 1387

PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 May 2015. The Schedule is updated on the first day of each month and is available on the Internet at www.pbs.gov.au.

Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 May 2015 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	\$6.76
	Dangerous drug fee	\$2.71
	Extemporaneously-prepared	\$8.80
	Allowable additional patient charge*	\$4.27
Additional Fees (for safety net prices):	Ready-prepared	\$1.15
	Extemporaneously-prepared	\$1.50
Patient Co-payments:	General	\$37.70
	Concessional	\$6.10
Safety Net Thresholds:	General	\$1453.90
	Concessional	\$366.00
Safety Net Card Issue Fee:		\$9.47

* The allowable additional patient charge is a discretionary charge to general patients if a pharmaceutical item has a dispensed price for maximum quantity less than the general patient co-payment. The pharmacist may charge general patients the allowable additional fee but the fee cannot take the cost of the prescription above the general patient co-payment for the medicine. This fee does not count towards the Safety Net threshold.

Prescriber Bag

Deletions

Deletion – Item

10016E **BENZTROPINE**, benzotropine mesylate 2 mg/2 mL injection, 10 x 2 mL vials (*Benzotropine Omega*)

General Pharmaceutical Benefits

Additions

Addition – Item

10255R **LEUPRORELIN**, leuporelin acetate 30 mg injection: modified release [1 syringe] (&) inert substance diluent [1 syringe], 1 pack (*Lucrin Depot Paediatric 30 mg PDS*)
 10256T **LEUPRORELIN**, leuporelin acetate 30 mg injection: modified release [1 syringe] (&) inert substance diluent [1 syringe], 1 pack (*Lucrin Depot Paediatric 30 mg PDS*)
 10257W **MESALAZINE**, mesalazine 3 g granules, 30 sachets (*Salofalk*)

Addition – Brand

8214H *Blooms the Chemist Atorvastatin, IB* – **ATORVASTATIN**, atorvastatin 20 mg tablet, 30
 9231W *Blooms the Chemist Atorvastatin, IB* – **ATORVASTATIN**, atorvastatin 20 mg tablet, 30
 8215J *Blooms the Chemist Atorvastatin, IB* – **ATORVASTATIN**, atorvastatin 40 mg tablet, 30
 9232X *Blooms the Chemist Atorvastatin, IB* – **ATORVASTATIN**, atorvastatin 40 mg tablet, 30
 8521L *Blooms the Chemist Atorvastatin, IB* – **ATORVASTATIN**, atorvastatin 80 mg tablet, 30
 9233Y *Blooms the Chemist Atorvastatin, IB* – **ATORVASTATIN**, atorvastatin 80 mg tablet, 30
 2688L *Azathioprine GH, GQ* – **AZATHIOPRINE**, azathioprine 25 mg tablet, 100
 2687K *Azathioprine GH, GQ* – **AZATHIOPRINE**, azathioprine 50 mg tablet, 100
 8703C *Citalopram Actavis, VN* – **CITALOPRAM**, citalopram 40 mg tablet, 28
 3138E *Clindamycin-Link, LM* – **CLINDAMYCIN**, clindamycin 150 mg capsule, 24
 5057E *Clindamycin-Link, LM* – **CLINDAMYCIN**, clindamycin 150 mg capsule, 24 (**Dental**)
 9296G *Piax Plus Aspirin, AF* – **CLOPIDOGREL + ASPIRIN**, clopidogrel 75 mg + aspirin 100 mg tablet, 30
 5472B *Zilfojim ODT 4, DO* – **ONDANSETRON**, ONDANSETRON Tablet (orally disintegrating) 4 mg, 10
 5473C *Zilfojim ODT 8, DO* – **ONDANSETRON**, ONDANSETRON Tablet (orally disintegrating) 8 mg, 10
 2242B *Paroxetine Actavis, UA* – **PAROXETINE**, paroxetine 20 mg tablet, 30
 9151P *APO-Pramipexole, TX* – **PRAMIPEXOLE**, pramipexole hydrochloride monohydrate 125 microgram tablet, 30
 9152Q *APO-Pramipexole, TX* – **PRAMIPEXOLE**, pramipexole hydrochloride monohydrate 250 microgram tablet, 100
 9153R *APO-Pramipexole, TX* – **PRAMIPEXOLE**, pramipexole hydrochloride monohydrate 1 mg tablet, 100
 2833D *Auro-Pravastatin 10, DO* – **PRAVASTATIN**, pravastatin sodium 10 mg tablet, 30
 9237E *Auro-Pravastatin 10, DO* – **PRAVASTATIN**, pravastatin sodium 10 mg tablet, 30
 2834E *Auro-Pravastatin 20, DO* – **PRAVASTATIN**, pravastatin sodium 20 mg tablet, 30
 9238F *Auro-Pravastatin 20, DO* – **PRAVASTATIN**, pravastatin sodium 20 mg tablet, 30
 8197K *Auro-Pravastatin 40, DO* – **PRAVASTATIN**, pravastatin sodium 40 mg tablet, 30
 9239G *Auro-Pravastatin 40, DO* – **PRAVASTATIN**, pravastatin sodium 40 mg tablet, 30
 8829Q *Auro-Pravastatin 80, DO* – **PRAVASTATIN**, pravastatin sodium 80 mg tablet, 30
 9240H *Auro-Pravastatin 80, DO* – **PRAVASTATIN**, pravastatin sodium 80 mg tablet, 30
 9120B *Vascalace Caps 1.25, DO* – **RAMIPRIL**, ramipril 1.25 mg capsule, 30
 9121C *Vascalace Caps 2.5, DO* – **RAMIPRIL**, ramipril 2.5 mg capsule, 30
 9122D *Vascalace Caps 5, DO* – **RAMIPRIL**, ramipril 5 mg capsule, 30
 8470T *Vascalace Caps 10, DO* – **RAMIPRIL**, ramipril 10 mg capsule, 30
 9368C *Dilart, AF* – **VALSARTAN**, valsartan 40 mg tablet, 28
 9369D *Dilart, AF* – **VALSARTAN**, valsartan 80 mg tablet, 28
 9370E *Dilart, AF* – **VALSARTAN**, valsartan 160 mg tablet, 28
 9371F *Dilart, AF* – **VALSARTAN**, valsartan 320 mg tablet, 28
 9372G *Dilart HCT 80/12.5, AF* – **VALSARTAN + HYDROCHLOROTHIAZIDE**, valsartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28
 9373H *Dilart HCT 160/12.5, AF* – **VALSARTAN + HYDROCHLOROTHIAZIDE**, valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28
 9374J *Dilart HCT 160/25, AF* – **VALSARTAN + HYDROCHLOROTHIAZIDE**, valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28
 9481B *Dilart HCT 320/12.5, AF* – **VALSARTAN + HYDROCHLOROTHIAZIDE**, valsartan 320 mg + hydrochlorothiazide 12.5 mg tablet, 28
 9482C *Dilart HCT 320/25, AF* – **VALSARTAN + HYDROCHLOROTHIAZIDE**, valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28

Addition – Equivalence Indicator

9372G *Co-Diovan 80/12.5, NV* – **VALSARTAN + HYDROCHLOROTHIAZIDE**, valsartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28
 9374J *Co-Diovan 160/25, NV* – **VALSARTAN + HYDROCHLOROTHIAZIDE**, valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28

Deletions

Deletion – Item

10013B	BENZTROPINE , benztropine mesylate 2 mg/2 mL injection, 10 x 2 mL vials (<i>Benztropine Omega</i>)
10027R	BENZTROPINE , benztropine mesylate 2 mg/2 mL injection, 10 x 2 mL vials (<i>Benztropine Omega</i>) (Dental)
2058H	CARBOMER + TRIGLYCERIDE LIPIDS , carbomer 0.2% + triglyceride lipids 1% eye gel, 30 x 600 mg unit doses (<i>Artelac</i>)
2090B	CARBOMER + TRIGLYCERIDE LIPIDS , carbomer 0.2% + triglyceride lipids 1% eye gel, 30 x 600 mg unit doses (<i>Artelac</i>) (Optometrical)
8652J	MYCOPHENOLATE , mycophenolate 180 mg tablet: enteric, 120 tablets (<i>Myfortic</i>)
8653K	MYCOPHENOLATE , mycophenolate 360 mg tablet: enteric, 120 tablets (<i>Myfortic</i>)
1742Q	OESTRADIOL , oestradiol 25 microgram pessary: modified release, 15 (<i>Vagifem</i>)
9004X	TESTOSTERONE UNDECANOATE , testosterone undecanoate 1 g/4 mL injection, 1 x 4 mL ampoule (<i>Reandron 1000</i>)

Deletion – Brand

1007B	<i>Acihexal</i> , SZ – ACICLOVIR , aciclovir 200 mg tablet, 90
1171P	<i>Chloromycetin</i> , PF – CHLORAMPHENICOL , chloramphenicol 1% eye ointment, 4 g
5511C	<i>Chloromycetin</i> , PF – CHLORAMPHENICOL , chloramphenicol 1% eye ointment, 4 g (Optometrical)
1473M	<i>Fluconazole-Claris</i> , AE – FLUCONAZOLE , fluconazole 100 mg/50 mL injection, 1 x 50 mL vial
1474N	<i>Fluconazole-Claris</i> , AE – FLUCONAZOLE , fluconazole 200 mg/100 mL injection, 1 x 100 mL vial
2414C	<i>Frusemide AN</i> , EA – FRUSEMIDE , frusemide 20 mg tablet, 100
2412Y	<i>Frusemide AN</i> , EA – FRUSEMIDE , frusemide 40 mg tablet, 100
8534E	<i>Lercanidipine AN</i> , EA – LERCANIDIPINE , lercanidipine hydrochloride 10 mg tablet, 28
8679T	<i>Lercanidipine AN</i> , EA – LERCANIDIPINE , lercanidipine hydrochloride 20 mg tablet, 28
1627P	<i>Tolvon</i> , MK – MIANSERIN , mianserin hydrochloride 10 mg tablet, 50
8525Q	<i>Lodam SR 200</i> , ZP – TRAMADOL , tramadol hydrochloride 200 mg tablet: modified release, 20 tablets

Deletion – Equivalence Indicator

1627P	<i>Lumin 10</i> , AF – MIANSERIN , mianserin hydrochloride 10 mg tablet, 50

Alterations

Changes to Restrictions

The following items have additions, deletions or alterations to restrictions and/or notes.

8845M	BALSALAZIDE , balsalazide sodium 750 mg capsule, 180 (<i>Colazide</i>)
1502C	HYDROCORTISONE ACETATE , hydrocortisone acetate 10% (100 mg/g) enema, 21.1 g (<i>Colifoam</i>)
1611T	MESALAZINE , mesalazine 250 mg tablet: enteric, 100 tablets (<i>Mesasal</i>)
2214M	MESALAZINE , mesalazine 500 mg tablet: modified release, 100 tablets (<i>Pentasa</i>)
2234N	MESALAZINE , mesalazine 1 g granules: modified release, 120 x 1 g sachets (<i>Pentasa</i>)
2287J	MESALAZINE , mesalazine 2 g granules: modified release, 60 x 2 g sachets (<i>Pentasa</i>)
3413P	MESALAZINE , mesalazine 1 g tablet: modified release, 60 tablets (<i>Pentasa</i>)
5461K	MESALAZINE , mesalazine 1 g suppository, 30 (<i>Salofalk</i>)
8598M	MESALAZINE , mesalazine 500 mg granules, 100 x 500 mg sachets (<i>Salofalk</i>)
8599N	MESALAZINE , mesalazine 1 g granules: modified release, 100 x 1 g sachets (<i>Salofalk</i>)
8616L	MESALAZINE , mesalazine 2 g/60 mL enema, 7 x 60 mL (<i>Salofalk</i>)
8617M	MESALAZINE , mesalazine 4 g/60 mL enema, 7 x 60 mL (<i>Salofalk</i>)
8731M	MESALAZINE , mesalazine 500 mg tablet: enteric, 100 tablets (<i>Salofalk</i>)
8752P	MESALAZINE , mesalazine 1 g suppository, 30 (<i>Pentasa</i>)
8753Q	MESALAZINE , mesalazine 1 g/100 mL enema, 7 x 100 mL (<i>Pentasa</i>)
8768L	MESALAZINE , mesalazine 1 g/application enema, 14 applications (<i>Salofalk</i>)
9206M	MESALAZINE , mesalazine 1.5 g granules, 60 x 1.5 g sachets (<i>Salofalk</i>)
9353G	MESALAZINE , mesalazine 1.2 g tablet: modified release, 60 tablets (<i>Mezavant</i>)
1728Y	OLSALAZINE , olsalazine sodium 250 mg capsule, 100 (<i>Dipentum</i>)
8086N	OLSALAZINE , olsalazine sodium 500 mg tablet, 100 (<i>Dipentum</i>)
1920C	PREDNISOLONE SODIUM PHOSPHATE , prednisolone (as sodium phosphate) 20 mg/100 mL enema, 7 x 100 mL (<i>Predsol</i>)
2554K	PREDNISOLONE SODIUM PHOSPHATE , prednisolone (as sodium phosphate) 5 mg suppository, 10 (<i>Predsol</i>)
2574L	ROSUVASTATIN , rosuvastatin 20 mg tablet, 30 (<i>APO-Rosuvastatin</i> , <i>Blooms the Chemist Rosuvastatin</i> , <i>Cavstat</i> , <i>Chem mart Rosuvastatin</i> , <i>Crestor</i> , <i>Crosuva 20</i> , <i>Rosuvastatin Actavis 20</i> , <i>Rosuvastatin GH</i> , <i>Rosuvastatin-DRLA</i> , <i>Terry White Chemists Rosuvastatin</i>)
2606E	ROSUVASTATIN , rosuvastatin 5 mg tablet, 30 (<i>APO-Rosuvastatin</i> , <i>Blooms the Chemist Rosuvastatin</i> , <i>Cavstat</i> , <i>Chem mart Rosuvastatin</i> , <i>Crestor</i> , <i>Crosuva 5</i> , <i>Rosuvastatin Actavis 5</i> , <i>Rosuvastatin GH</i> , <i>Rosuvastatin-DRLA</i> , <i>Terry White Chemists Rosuvastatin</i>)
2628H	ROSUVASTATIN , rosuvastatin 10 mg tablet, 30 (<i>APO-Rosuvastatin</i> , <i>Blooms the Chemist Rosuvastatin</i> , <i>Cavstat</i> , <i>Chem mart Rosuvastatin</i> , <i>Crestor</i> , <i>Crosuva 10</i> , <i>Rosuvastatin Actavis 10</i> , <i>Rosuvastatin GH</i> , <i>Rosuvastatin-DRLA</i> , <i>Terry White Chemists Rosuvastatin</i>)
9042X	ROSUVASTATIN , rosuvastatin 5 mg tablet, 30 (<i>APO-Rosuvastatin</i> , <i>Blooms the Chemist Rosuvastatin</i> , <i>Cavstat</i> , <i>Chem mart Rosuvastatin</i> , <i>Crestor</i> , <i>Crosuva 5</i> , <i>Rosuvastatin AN</i> , <i>Rosuvastatin Actavis 5</i> , <i>Rosuvastatin GH</i> , <i>Rosuvastatin RBX</i> , <i>Rosuvastatin Sandoz</i> , <i>Rosuvastatin-DRLA</i> , <i>Terry White Chemists Rosuvastatin</i>)

9043Y	ROSUVASTATIN , rosuvastatin 10 mg tablet, 30 (APO-Rosuvastatin, Blooms the Chemist Rosuvastatin, Cavstat, Chem mart Rosuvastatin, Crestor, Crosva 10, Rostor 10, Rosuvastatin AN, Rosuvastatin Actavis 10, Rosuvastatin GH, Rosuvastatin Sandoz, Rosuvastatin-DRLA, Rosuvastatin RBX, Terry White Chemists Rosuvastatin)
9044B	ROSUVASTATIN , rosuvastatin 20 mg tablet, 30 (APO-Rosuvastatin, Blooms the Chemist Rosuvastatin, Cavstat, Chem mart Rosuvastatin, Crestor, Crosva 20, Rostor 20, Rosuvastatin Actavis 20, Rosuvastatin GH, Rosuvastatin RBX, Rosuvastatin Sandoz, Rosuvastatin-DRLA, Rosuvastatin AN, Terry White Chemists Rosuvastatin)
2093E	SULFASALAZINE , sulfasalazine 500 mg tablet, 100 (Salazopyrin)
2096H	SULFASALAZINE , SULFASALAZINE Tablet 500 mg (enteric coated), 100 (Pyralin EN, Salazopyrin-EN)
9208P	SULFASALAZINE , sulfasalazine 500 mg tablet, 100 (Salazopyrin)
9209Q	SULFASALAZINE , SULFASALAZINE Tablet 500 mg (enteric coated), 100 (Pyralin EN, Salazopyrin-EN)

Alteration – Restriction Level

		From streamlined	To restricted
8511Y	ALENDRONATE , alendronate 70 mg tablet, 4 (APO-Alendronate, Alendro Once Weekly, Alendrobell 70mg, Alendronate AN, Alendronate Sandoz, Alendronate-GA, Chem mart Alendronate 70mg, Densate 70, Fonat, Ossmax 70mg, Terry White Chemists Alendronate 70mg)		
8657P	CYCLOSPORIN , cyclosporin 10 mg capsule, 60 (Neoral 10)	authority-required	unrestricted
8658Q	CYCLOSPORIN , cyclosporin 25 mg capsule, 30 (Cyclosporin Sandoz, Neoral 25)	authority-required	unrestricted
8659R	CYCLOSPORIN , cyclosporin 50 mg capsule, 30 (Cyclosporin Sandoz, Neoral 50)	authority-required	unrestricted
8660T	CYCLOSPORIN , cyclosporin 100 mg capsule, 30 (Cyclosporin Sandoz, Neoral 100)	authority-required	unrestricted
8661W	CYCLOSPORIN , cyclosporin 100 mg/mL oral liquid, 50 mL (Neoral)	authority-required	unrestricted
9184J	FLUDARABINE , fludarabine phosphate 10 mg tablet, 20 (Fludara)	authority-required	unrestricted
8726G	GLATIRAMER ACETATE , glatiramer acetate 20 mg/mL injection, 28 x 1 mL syringes (Copaxone)	authority-required	streamlined
1454M	GOSERELIN , goserelin 3.6 mg implant, 1 (Zoladex Implant)	authority-required	restricted
8093Y	GOSERELIN , goserelin 10.8 mg implant, 1 (Zoladex 10.8 Implant)	streamlined	restricted
9064C	GOSERELIN (&) BICALUTAMIDE , goserelin 3.6 mg implant [1 implant] (&) bicalutamide 50 mg tablet [28 tablets], 1 pack (ZolaCos CP 3.6/50)	streamlined	restricted
9065D	GOSERELIN (&) BICALUTAMIDE , goserelin 10.8 mg implant [1 implant] (&) bicalutamide 50 mg tablet [28 tablets], 1 pack (ZolaCos CP 10.8/50(28))	streamlined	restricted
9066E	GOSERELIN (&) BICALUTAMIDE , goserelin 10.8 mg implant [1 implant] (&) bicalutamide 50 mg tablet [84 tablets], 1 pack (ZolaCos CP 10.8/50(84))	streamlined	restricted
8289G	INTERFERON BETA-1A , interferon beta-1a 30 microgram (6 million international units) injection [4 x 30 microgram vials] (&) inert substance diluent [4 x 1.1 mL syringes], 1 pack (Avonex)	authority-required	streamlined
8403G	INTERFERON BETA-1A , interferon beta-1a 44 microgram/0.5 mL (12 million international units) injection, 12 x 0.5 mL syringes (Rebif 44)	authority-required	streamlined
8805K	INTERFERON BETA-1A , interferon beta-1a 30 microgram/0.5 mL (6 million international units) injection, 4 x 0.5 mL syringes (Avonex)	authority-required	streamlined
8968B	INTERFERON BETA-1A , INTERFERON BETA-1a Injection 44 micrograms (12,000,000 i.u.) in 0.5 mL single dose autoinjector, 12 (Rebif 44)	authority-required	streamlined
9332E	INTERFERON BETA-1A , interferon beta-1a 44 microgram/0.5 mL (12 million international units) injection, 4 x 1.5 mL cartridges (Rebif 44)	authority-required	streamlined
8101J	INTERFERON BETA-1B , interferon beta-1b 8 million international units (250 microgram) injection [15 x 250 microgram vials] (&) inert substance diluent [15 x 1.2 mL syringes], 1 pack (Betaferon)	authority-required	streamlined
1836P	MYCOPHENOLATE , mycophenolate Capsule 250 mg, 50 (Ceptolate)	authority-required	unrestricted
2150E	MYCOPHENOLATE , mycophenolate 180 mg tablet: enteric, 120 tablets (Myfortic)	authority-required	unrestricted
2193K	MYCOPHENOLATE , mycophenolate 360 mg tablet: enteric, 120 tablets (Myfortic)	authority-required	unrestricted
8649F	MYCOPHENOLATE , mycophenolate mofetil 250 mg capsule, 100 (APO-Mycophenolate, CellCept, Mycophenolate Sandoz, Pharmacor Mycophenolate 250)	authority-required	unrestricted
8650G	MYCOPHENOLATE , mycophenolate mofetil 500 mg tablet, 50 (APO-Mycophenolate, CellCept, Ceptolate, Pharmacor Mycophenolate 500, Mycophenolate Sandoz)	authority-required	unrestricted
8651H	MYCOPHENOLATE , mycophenolate mofetil 1 g/5 mL oral liquid: powder for, 165 mL (CellCept)	authority-required	unrestricted
8209C	PAMIDRONATE DISODIUM , pamidronate disodium 30 mg injection [2 x 30 mg vials] (&) inert substance diluent [2 x 10 mL ampoules], 1 pack (Aredia 30 mg)	streamlined	restricted
8461H	PAMIDRONATE DISODIUM , pamidronate disodium 15 mg/5 mL injection, 1 x 5 mL vial (Pamisol)	streamlined	restricted
8462J	PAMIDRONATE DISODIUM , pamidronate disodium 30 mg/10 mL injection, 1 x 10 mL vial (Pamisol)	streamlined	restricted

8463K	PAMIDRONATE DISODIUM , pamidronate disodium 60 mg/10 mL injection, 1 x 10 mL vial (<i>Pamisol</i>)	streamlined	restricted
8481J	RISEDRONATE , risedronate sodium 5 mg tablet, 28 (<i>Actonel</i>)	streamlined	restricted
8482K	RISEDRONATE , risedronate sodium 30 mg tablet, 28 (<i>Actonel</i>)	streamlined	restricted
8621R	RISEDRONATE , risedronate sodium 35 mg tablet, 4 (<i>APO-Risedronate, Acris Once-a-Week, Risedro once a week, Risedronate AN, Risedronate Sandoz, Risedronate-GA</i>)	streamlined	restricted
8972F	RISEDRONATE , RISEDRONATE SODIUM Tablet 35 mg (enteric coated), 4 (<i>Actonel EC</i>)	streamlined	restricted
9391G	RISEDRONATE , risedronate sodium 150 mg tablet, 1 (<i>APO-Risedronate, Acris Once-a-Month, Actonel Once-a-Month, Chem mart Risedronate, Terry White Chemists Risedronate</i>)	streamlined	restricted
8724E	SIROLIMUS , sirolimus 1 mg tablet, 100 (<i>Rapamune</i>)	authority-required	unrestricted
8725F	SIROLIMUS , sirolimus 1 mg/mL oral liquid, 60 mL (<i>Rapamune</i>)	authority-required	unrestricted
8833X	SIROLIMUS , sirolimus 2 mg tablet, 100 (<i>Rapamune</i>)	authority-required	unrestricted
8984W	SIROLIMUS , sirolimus 500 microgram tablet, 100 (<i>Rapamune</i>)	authority-required	unrestricted
5299X	TACROLIMUS , tacrolimus 500 microgram capsule: modified release, 30 capsules (<i>Prograf XL</i>)	authority-required	unrestricted
5300Y	TACROLIMUS , tacrolimus 1 mg capsule: modified release, 60 capsules (<i>Prograf XL</i>)	authority-required	unrestricted
5451X	TACROLIMUS , tacrolimus 5 mg capsule: modified release, 30 capsules (<i>Prograf XL</i>)	authority-required	unrestricted
8646C	TACROLIMUS , tacrolimus 500 microgram capsule, 100 (<i>Pharmacor Tacrolimus 0.5, Prograf, Tacrolimus Sandoz</i>)	authority-required	unrestricted
8647D	TACROLIMUS , tacrolimus 1 mg capsule, 100 (<i>Pharmacor Tacrolimus 1, Prograf, Tacrolimus Sandoz</i>)	authority-required	unrestricted
8648E	TACROLIMUS , tacrolimus 5 mg capsule, 50 (<i>Pharmacor Tacrolimus 5, Prograf, Tacrolimus Sandoz</i>)	authority-required	unrestricted
10062N	TEMOZOLOMIDE , temozolomide 180 mg capsule, 5 (<i>Astromide, Orion Temozolomide, Temodal</i>)	authority-required	restricted
2438H	TEMOZOLOMIDE , temozolomide 180 mg capsule, 5 (<i>Astromide, Orion Temozolomide, Temodal</i>)	authority-required	unrestricted
8378Y	TEMOZOLOMIDE , temozolomide 5 mg capsule, 5 (<i>Astromide, Orion Temozolomide, Temizole 5, Temodal, Temozolomide AN, Temozolomide Alphapharm</i>)	authority-required	unrestricted
8379B	TEMOZOLOMIDE , temozolomide 20 mg capsule, 5 (<i>Astromide, Orion Temozolomide, Temizole 20, Temodal, Temozolomide Alphapharm, Temozolomide AN</i>)	authority-required	unrestricted
8380C	TEMOZOLOMIDE , temozolomide 100 mg capsule, 5 (<i>Astromide, Orion Temozolomide, Temizole 100, Temodal, Temozolomide AN, Temozolomide Alphapharm</i>)	authority-required	unrestricted
8381D	TEMOZOLOMIDE , temozolomide 250 mg capsule, 5 (<i>Astromide, Orion Temozolomide, Temizole 250, Temodal, Temozolomide Alphapharm, Temozolomide AN</i>)	authority-required	unrestricted
8819E	TEMOZOLOMIDE , temozolomide 5 mg capsule, 5 (<i>Astromide, Orion Temozolomide, Temizole 5, Temodal, Temozolomide Alphapharm, Temozolomide AN</i>)	authority-required	restricted
8820F	TEMOZOLOMIDE , temozolomide 20 mg capsule, 5 (<i>Astromide, Orion Temozolomide, Temizole 20, Temodal, Temozolomide AN, Temozolomide Alphapharm</i>)	authority-required	restricted
8821G	TEMOZOLOMIDE , temozolomide 100 mg capsule, 5 (<i>Astromide, Orion Temozolomide, Temizole 100, Temodal, Temozolomide Alphapharm, Temozolomide AN</i>)	authority-required	restricted
9361Q	TEMOZOLOMIDE , temozolomide 140 mg capsule, 5 (<i>Astromide, Orion Temozolomide, Temizole 140, Temodal, Temozolomide Alphapharm</i>)	authority-required	restricted
9362R	TEMOZOLOMIDE , temozolomide 140 mg capsule, 5 (<i>Astromide, Orion Temozolomide, Temizole 140, Temodal, Temozolomide Alphapharm, Temozolomide AN</i>)	authority-required	unrestricted
8267D	TILUDRONATE , tiludronate 200 mg tablet, 56 (<i>Skelid</i>)	streamlined	restricted
9350D	ZOLEDRONIC ACID , zoledronic acid 5 mg/100 mL injection, 1 x 100 mL vial (<i>Aclasta</i>)	authority-required	streamlined

Alteration – Manufacturer Code

		<i>From</i>	<i>To</i>
8726G	<i>Copaxone</i> – GLATIRAMER ACETATE , glatiramer acetate 20 mg/mL injection, 28 x 1 mL syringes	CS	TB
9475Q	<i>Sculptra</i> – POLYLACTIC ACID , polylactic acid 150 mg injection, 1 x 150 mg vial	SW	GA
9476R	<i>Sculptra</i> – POLYLACTIC ACID , polylactic acid 150 mg injection, 1 x 150 mg vial	SW	GA

Alteration – Number of Repeats

		<i>From</i>	<i>To</i>
1836P	MYCOPHENOLATE , mycophenolate Capsule 250 mg, 50 (<i>Ceptolate</i>)	3	5
8649F	MYCOPHENOLATE , mycophenolate mofetil 250 mg capsule, 100 (<i>APO-Mycophenolate, CellCept, Mycophenolate Sandoz, Pharmacor Mycophenolate 250</i>)	3	5
8650G	MYCOPHENOLATE , mycophenolate mofetil 500 mg tablet, 50 (<i>APO-Mycophenolate, CellCept, Ceptolate, Pharmacor Mycophenolate 500, Mycophenolate Sandoz</i>)	3	5

8651H **MYCOPHENOLATE**, mycophenolate mofetil 1 g/5 mL oral liquid: powder for, 165 mL (*CellCept*)

3

5

Advance Notices

1 June 2015

Deletion – Brand

1172Q *Chloromycetin, PF* – **CHLORAMPHENICOL**, chloramphenicol 0.5% ear drops, 5 mL
 1210Q *Ciproxin 750, BN* – **CIPROFLOXACIN**, ciprofloxacin 750 mg tablet, 14

1 July 2015

Deletion – Brand

1783W *Ceftriaxone ICP, PP* – **CEFTRIAXONE**, ceftriaxone 500 mg injection, 1 x 500 mg vial
 9058R *Ceftriaxone ICP, PP* – **CEFTRIAXONE**, ceftriaxone 500 mg injection, 1 x 500 mg vial

1 August 2015

Deletion – Brand

2873F *Invokana, JC* – **CANAGLIFLOZIN**, canagliflozin 100 mg tablet, 30
 2987F *Invokana, JC* – **CANAGLIFLOZIN**, canagliflozin 300 mg tablet, 30
 9157Y *Sensipar, AN* – **CINACALCET**, cinacalcet 30 mg tablet, 28
 9158B *Sensipar, AN* – **CINACALCET**, cinacalcet 60 mg tablet, 28
 9159C *Sensipar, AN* – **CINACALCET**, cinacalcet 90 mg tablet, 28

Highly Specialised Drugs Program (Public Hospital)

Alterations

Changes to Restrictions

The following items have additions, deletions or alterations to restrictions and/or notes.

10109C **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 x 1 mL syringe (*Xolair*)
 10118M **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 1 x 0.5 mL syringe (*Xolair*)

Advance Notices

1 August 2015

Deletion – Brand

5621W *Sensipar, AN* – **CINACALCET**, cinacalcet 30 mg tablet, 28
 5622X *Sensipar, AN* – **CINACALCET**, cinacalcet 60 mg tablet, 28
 5623Y *Sensipar, AN* – **CINACALCET**, cinacalcet 90 mg tablet, 28

Highly Specialised Drugs Program (Private Hospital)

Alterations

Changes to Restrictions

The following items have additions, deletions or alterations to restrictions and/or notes.

10110D **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 1 x 0.5 mL syringe (*Xolair*)
 10122R **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 x 1 mL syringe (*Xolair*)

Advance Notices

1 August 2015

Deletion – Brand

9625N *Sensipar, AN* – **CINACALCET**, cinacalcet 30 mg tablet, 28
 9626P *Sensipar, AN* – **CINACALCET**, cinacalcet 60 mg tablet, 28
 9627Q *Sensipar, AN* – **CINACALCET**, cinacalcet 90 mg tablet, 28

Addresses — Department of Human Services

The Department of Human Services has responsibility for the operational aspects of the Pharmaceutical Benefits Scheme (PBS). This responsibility covers the processing of pharmaceutical benefit and safety net claims, authority applications and supply of PBS stationery used by medical practitioners, participating dental practitioners and approved pharmacists.

Procedures for ordering prescription forms are set out in the Introduction of this Schedule.

New South Wales and Australian Capital Territory

Pharmaceutical Benefits Branch
130 George Street
Parramatta NSW 2150

General and IME enquiries — Tel: 132 290

Orange Service Centre
189 Anson Street
Orange NSW 2800

General and IME enquiries — Tel: 132 290

Victoria

Pharmaceutical Branch
Level 10
595 Collins Street
Melbourne Vic 3000

General and IME enquiries — Tel: 132 290

Queensland

Pharmaceutical Services Branch
143 Turbot Street
Brisbane Qld 4000

General and IME enquiries — Tel: 132 290

Western Australia

Pharmaceutical Benefits Branch
Level 5, Work Distribution Centre,
(Reception on Level 4)
130 Stirling Street
Northbridge WA 6003

General and IME enquiries — Tel: 132 290

South Australia and Northern Territory

Pharmaceutical Services Branch
209 Greenhill Road
Eastwood SA 5063

General and IME enquiries — Tel: 132 290

Tasmania

Pharmaceutical Branch
199 Collins Street
Hobart Tas 7000

General and IME enquiries — Tel: 132 290

National Program Management

Pharmaceutical Benefits Branch
Department of Human Services
134 Reed Street
Greenway ACT 2900
Telephone — (02) 6124 6333
Website — www.humanservices.gov.au Email — pbs@humanservices.gov.au

Authority Prescription Applications

Authority required benefits fall into two categories – *Authority required* and *Authority required (STREAMLINED)*. The process in which an authority PBS prescription can be prescribed will depend on the type of Authority required benefit.

Prior approval is required for Authority required items as well as all requests for increased quantities and/or repeats for any category of PBS item.

Prior approval is not required for Authority required (STREAMLINED) items except if increased quantities and/or repeats are required (see Explanatory Notes for details).

Mail Applications:

REPLY PAID No. 9857
PBS Authorities Section
Department of Human Services
GPO Box 9857
In your Capital City

Telephone Applications:

Free call 1800 888 333
Australia-wide 24 hour service PBS Authorities Section

For telephone applications please have the following information available:

Patient:

Medicare Number
Surname
First name
Full residential address (including post code)

PBS Authority Prescription Number:

Top right hand side of the handwritten PBS Authority Form

Your Prescriber Number:

Located below your address block on the personalised forms

Drug Information:

PBS item
Quantity required and number of repeats
Daily dose
Disease or purpose information

Requests for Drugs via the Special Access Scheme (SAS)

Requests for individual patient approval to obtain drugs that are available only through the SAS may be directed to a delegate within the Drug Safety and Evaluation Branch, Therapeutic Goods Administration, telephone (02) 6232 8111, facsimile (02) 6232 8112, or by mail to PO Box 100 Woden ACT 2606.

Department of Veterans' Affairs

Details of the approving authority for the Department of Veterans' Affairs are listed at the front of the Repatriation Schedule of Pharmaceutical Benefits.

Telephone Interpreter Service

A 24-hour, seven days a week telephone service is available by contacting 131 450.

The translating service (TIS) can provide immediate assistance over the telephone or arrange for an interpreter to go to a location specified in either city or country areas. The TIS service has access to 2000 professional interpreters, covering over 100 languages and dialects.

Poisons Information Centres

Phone 131 126 from anywhere in Australia — 24 hours — form information and advice on the treatment of poisoning, bites and stings

NSW

The New Children's Hospital
Hawkesbury Road
Westmead NSW 2148
Tel: (02) 9845 3111

VIC

Austin Hospital
Studley Road
Heidelberg VIC 3084
Tel: (03) 9496 4410
www.austin.org.au/poisons

QLD

Pharmacy Department
Royal Children's Hospital
Herston QLD 4029
Tel: 131 126

WA

Sir Charles Gairdner Hospital
Hospital Avenue
Nedlands WA 6009
Tel: 131 126

TAS

Tel: 131 126

NT

Tel: 131 126

ACT

Tel: 131 126

Drug Information Centres

NSW

Drug Information Pharmacist
New South Wales Medicines Information
Centre
PO Box 766
Darlinghurst NSW 2010
Tel: (02) 8382 2136

OR

Drug Information Pharmacist
Hunter Drug Information Service
Newcastle Mater Misericordiae Hospital
Locked Bag 7
Hunter Regional Mail Centre NSW 2310
Tel: (02) 4921 1278
Tel: (02) 4921 1328

VIC

Drug Information Pharmacist
Austin & Repatriation Medical Centre
Studley Road
Heidelberg Vic 3084
Tel: (03) 9496 5668

OR

Drug Information Pharmacist
Drug Information Centre
Southern Health Care Network
Monash Medical Centre
246 Clayton Road
Clayton Vic 3168
Tel: (03) 9594 2361

QLD

Assistant Director of Pharmacy
Queensland Drug Information Ctr
Royal Brisbane Hospital
E Floor, Block 7
Herston Road
Herston Qld 4029
Tel: (07) 3636 7098
(07) 3636 7599

SA

Drug Information Pharmacist
Royal Adelaide Hospital
North Terrace
Adelaide SA 5000
Tel: (08) 8222 5546

OR

Drug Information Pharmacist
Flinders Medical Centre
Bedford Park SA 5042
Tel: (08) 8204 5301

OR

Drug Information Pharmacist
Queen Elizabeth Hospital
Woodville Road
Woodville SA 5011
Tel: (08) 8222 6777

WA

Drug Information Pharmacist
Sir Charles Gairdner Hospital
Hospital Avenue
Nedlands WA 6009
Tel: (08) 9346 2923

TAS

Drug Information Pharmacist
Royal Hobart Hospital
GPO Box 1061L
Hobart Tas 7001
Tel: (03) 6222 8737

NT

Drug Information Pharmacist
Royal Darwin Hospital
PO Box 41326
Casuarina NT 0811
Tel: (08) 8922 8424

ACT

Drug Information Pharmacist
Canberra Hospital
Yamba Drive
Garran ACT 2605
Tel: (02) 6244 3333

List of Contact Officers for Recalls of Therapeutic Goods

For details of consumer level recalls only — telephone 1800 020 512

These officers may be contacted —

- to obtain information about current recalls
- to report suspected problems relating to the quality, safety or efficacy of a therapeutic good

Australian Recall Coordinator

Mr Mick O'Connor

Bh 02 6232 8197
Mobile 0421 583 361
Fax 02 6203 1451
E-mail recalls@tga.gov.au

Australian Capital Territory

Mr Michael Conroy

Bh 02 6207 3974
Mobile 0418 182 375
Fax 02 6205 0997
E-mail pharmaceuticalservices@act.gov.au
 MichaelJ.Conroy@act.gov.au

New South Wales

Mr B. Battye

Bh 02 9879 3214
Mobile 0401 712 050
Fax 02 9859 5165
E-mail bruce.battye@doh.health.nsw.gov.au

Ms J. Mackson

Bh 02 9879 3214
Mobile 0411 145 562
Fax 02 9859 5165
E-mail jmack@doh.health.nsw.gov.au

Victoria

Ms M. Smith

Bh 03 9096 5355
Bh 1300 364 545
Mobile 0408 598 663
Fax 1300 360 830
E-mail megan.l.smith@health.vic.gov.au

Mr M. McCrone

Bh 03 9096 5066
Bh 1300 364 545
Mobile 0408 581 312
Fax 1300 360 830
E-mail matthew.mccrone@health.vic.gov.au

Queensland

Mr C.J. Healey

Bh 07 3328 9310
Mobile 0403 053 090
Fax 07 3328 9354
E-mail chris_healey@health.qld.gov.au

Mr A. Hawkins

Bh 07 3328 9310
Mobile 0449 267 625
Fax 07 3228 9354
E-mail andrew_hawkins@health.qld.gov.au

South Australia

Mr S. Morris

Bh 08 8204 1940
Mobile 0431 657 090
Fax 08 8226 9837
E-mail steve.morris@health.sa.gov.au

Ms E. Hender

Bh 0418 747 833
Mobile 0431 657 090
Fax 08 8226 9837
E-mail elizabeth.hender@health.sa.gov.au

Western Australia

Mr Neil Keen

Bh 08 9222 6883
Mobile 0419 944 801
Fax 08 9222 2463
E-mail neil.keen@health.wa.gov.au
 poisons@health.wa.gov.au

Tasmania

Ms M. Sharpe

Bh 03 6233 3766
Ah 03 6223 3476
Fax 03 6233 3904
E-mail mary.sharpe@dhhs.tas.gov.au

Mr J. Galloway

Bh 03 6233 2064
Ah 03 6223 7074
Fax 03 6233 3904
E-mail james.galloway@dhhs.tas.gov.au

Northern Territory

Ms Helgi Stone

Bh 08 8922 7035
Mobile 0429 091 636
Fax 08 8922 7200
E-mail Helgi.stone@nt.gov.au

Mr T. DeSilva

Bh 08 8922 7340
Mobile 0400 251 419
Fax 08 8922 7200
E-mail tyronne.dezilva@nt.gov.au

Index of Manufacturers' codes

Code	Manufacturer
AB	Abbott Australasia Pty Ltd Sir Joseph Banks Corporate Park 32-34 Lord Street BOTANY NSW 2019 Tel: 1800 801 478
AE	AFT Pharmaceuticals Pty Ltd Level 1 296 Burns Bay Road LANE COVE NSW 2066 Tel: 1800 097 639
AF	Alphapharm Pty Ltd Level 1 30 The Bond, 30-34 Hickson Rd MILLERS POINT NSW 2000 Tel: 1800 028 365
AG	Allergan Australia Pty Limited Level 4, 810 Pacific Highway Gordon NSW 2072 Tel: 1800 252 224
AL	Alphapharm Pty Ltd Level 1 30 The Bond, 30-34 Hickson Rd MILLERS POINT NSW 2000 Tel: 1800 028 365
AN	Amgen Australia Pty Limited Avaya House Level 7, 123 Epping Road NORTH RYDE NSW 2113 Tel: 1800 803 638
AP	AstraZeneca Pty Ltd Alma Road NORTH RYDE NSW 2113 Tel: 1800 805 342
AQ	Alcon Laboratories (Australia) Pty Ltd 10/25 Frenchs Forest Road East FRENCHS FOREST NSW 2086 Tel: 1800 025 032
AS	Aspen Pharmacare Australia Pty Limited 34-36 Chandos Street ST LEONARDS NSW 2065 Tel: (02) 8436 8300
AT	Actelion Pharmaceuticals Australia Pty Ltd Suite 6 13b Narabang Way Belrose NSW 2085 Tel: (02) 9486 4600
AV	sanofi-aventis Australia Pty Ltd Building D, Talavera Corporate Centre 12-24 Talavera Road Macquarie Park NSW 2113 Tel: +61 (0)2 8666 2000
BB	Blackmores Limited 20 Jubilee Avenue Warriewood NSW 2102 Tel: +61 (0)2 9910 5000 Fax: +61 (0)2 9910 5555

Code	Manufacturer
BD	Biogen Idec Australia Pty Ltd Suite 1, Level 5 123 Epping Road North Ryde NSW 2113 Tel: +61 (0)2 8875 3900
BE	Beiersdorf Australia Ltd 4 Khartoum Road North Ryde NSW 2113 Tel: +61 (0)2 9888 0977 Fax: +61 (0)2 9887 3487
BG	Sandoz Pty Ltd Suite 201, Level 2 19 Harris Street Pyrmont NSW 2009 Tel: 1800 726 369
BI	Biotech Pharmaceuticals Pty Ltd 83 Cherry Lane LAVERTON NORTH VIC 3026 Tel: (03) 9278 7555
BN	Bayer Australia Ltd 875 Pacific Highway Pymble NSW 2073 Tel: 1800 673 270
BQ	Bristol-Myers Squibb Australia Pty Ltd Level 2, 4 Nexus Court Mulgrave VIC 3170 Tel: 1800 067 567
BR	B. Braun Australia Pty Ltd Norwest Business Park 17 Lexington Drive BELLA VISTA NSW 2153 Tel: +61 (0)2 9629 0200
BV	B.S.N. 315 Ferntree Gully Road Mount Waverley VIC 3149 Tel: +61 (0)3 8540 6777
BX	Baxter Healthcare Pty Limited 1 Baxter Drive OLD TOONGABBIE NSW 2146 Tel: 1300 789 646
BY	Boehringer Ingelheim Pty Ltd 78 Waterloo Road NORTH RYDE NSW 2113 Tel: (02) 8875 8600
BZ	Boucher & Muir Pty Ltd Level 1, 134 Willoughby Road Crows Nest NSW 2065 Tel: 1800 627 680
CC	ConvaTec A Division of Bristol-Myers Squibb Australia Pty Ltd 606 Hawthorn Road East Brighton VIC 3187 Tel: 1800 335 276
CH	Apotex Pty Ltd 16 Giffnock Avenue MACQUARIE PARK NSW 2113 Tel: 1800 276 839

Index of Manufacturers' codes

Code	Manufacturer
CJ	Celgene Pty Limited Level 7 607 St Kilda Road MELBOURNE VIC 3044 Tel: (03) 9539 5500
CR	Pharmacor Pty Limited Suite 401 7 Oaks Avenue DeeWhy NSW 2099 Tel: 1300 138 805
CS	bioCSL (Australia) Pty Ltd 63 Poplar Road Parkville VIC 3052 Tel: 1800 008 275
CT	Coloplast Pty Ltd 33 Gilby Road Mount Waverley VIC 3149 Tel: 1800 673 317
CU	Care Pharmaceuticals Pty Limited Suite 303, Level 3, 59-75 Grafton Street Bondi Junction NSW 2022 Tel: 1800 788 870
CX	Contact Lens Centre Australia Limited Unit D6, Hallmarc Business Park Cnr Westall and Centre Roads CLAYTON VIC 3168 Tel: (03) 9543 1811
DO	Aurobindo Pharma (Australia) Pty Limited Unit 3 North RydeLink Business Park 277-283 Lane Cove Road Macquarie Park NSW 2113 Tel: +61 (0)2 9805 6000
DQ	Church & Dwight (Australia) Pty Ltd Unit 1/108 Old Pittwater Road Brookvale NSW 2100 Tel: 1800 222 099
DV	Medical Developments International Limited 6/56 Smith Road SPRINGVALE VIC 3171 Tel: (03) 9547 1888
EA	Amneal Pharmaceuticals Pty Ltd 12 River Street South Yarra VIC 3141 Tel: +61 (0)3 8849 1200 Fax: +61 (0)3 8849 1299
EH	Entra Health Systems Pty Ltd 12/60 Castlereagh Street SYDNEY NSW 2000 Tel: (02) 9846 6642
EI	Eisai Australia Pty Ltd Level 2, 437 St Kilda Road Melbourne VIC 3004 Tel: +61 (0)3 9832 9100
EL	Eli Lilly Australia Pty Ltd 112 Wharf Road West Ryde NSW 2114 Tel: (02) 9325 4444

Code	Manufacturer
EO	Ego Pharmaceuticals Proprietary Limited 21-31 Malcolm Road Braeside VIC 3195 Tel: (03) 9587 1088
ER	Eris Pharmaceuticals (Australia) Pty Ltd 6 Eastern Road South Melbourne VIC 3205 Tel: +61 (0)3 9690 8473 Fax: +61 (0)3 9690 8479
EU	Emerge Health Pty Ltd Suite 3, Level 1 2 Theatre Place Canterbury VIC 3126 Tel: +61 (0)3 9077 4486 Fax: +61 (0)3 8672 0792
EZ	Merz Australia Pty Ltd Level 3, 244 Coward Street Mascot NSW 2020 Tel:
FB	Pierre Fabre Medicament Australia Pty Ltd Unit 3B 1 Richardson Place NORTH RYDE NSW 2113 Tel: +61 (0)2 8662 9800
FI	Boehringer Ingelheim Pty Ltd 78 Waterloo Road NORTH RYDE NSW 2113 Tel: (02) 8875 8600
FK	A. Menarini Australia Pty Limited Level 8 67 Albert Avenue Chatswood NSW 2067 Tel: +61 (0)2 9080 7200
FM	Fawns and McAllan Proprietary Limited 34-36 Chandos Street ST LEONARDS NSW 2065 Tel: +61 (0)2 8436 8300
FN	Fresenius Medical Care Australia Pty Ltd Level 17, 61 Lavender Street Milsons Point NSW 2061 Tel: +61 (0)2 9466 8000 Fax: +61 (0)2 9929 5595
FO	For Benefit Medicines Pty Ltd 27 Kirrawee Road North Gosford NSW 2250 Tel:
FP	Ferring Pharmaceuticals Pty Limited Suite 2, Level 1, Building 1 Pymble Corporate Centre PYMBLE NSW 2073 Tel: +61 (0)2 9497 2300 Fax: +61 (0)2 9497 2399
FR	Merck Sharp & Dohme (Australia) Pty Ltd Level 1, Building A 26 Talavera Road MACQUARIE PARK NSW 2113 Tel: +61 (0)2 8988 8000

Index of Manufacturers' codes

Code	Manufacturer
FZ	Pfizer Australia Pty Ltd 38-42 Wharf Road West Ryde NSW 2114 Tel: +61 (0)2 9850 3333
GA	Galderma Australia Pty Ltd Suite 4, 13B Narabang Way Belrose NSW 2085 Tel: +61 (0)2 9479 0600
GC	GlaxoSmithKline Australia Pty Ltd Level 4, 436-438 Johnston Street Abbotsford VIC 3067 Tel: +61 (0)3 9721 8600
GH	Mercury Pharma (Australia) Pty Limited Level 1, 134 Willoughby Road Crows Nest NSW 2065 Tel: +61 (0)2 9431 6333
GI	Gilead Sciences Pty Limited Level 1, 128 Jolimont Road EAST MELBOURNE VIC 3002 Tel: (03) 9272 4400
GK	GlaxoSmithKline Australia Pty Ltd Level 4, 436-438 Johnston Street Abbotsford VIC 3067 Tel: +61 (0)3 9721 8600
GN	Actavis Pty Ltd Level 5, 117 Harrington Street The Rocks NSW 2000 Tel: 1800 678 302
GO	BGP Products Pty Ltd 299 Lane Cove Road Macquarie Park NSW 2113 Tel: 1800 225 311
GQ	Generic Health Pty Ltd Level 1, 1100-1102 Toorak Road CAMBERWELL VIC 3124 Tel: +61 (0)3 9809 7900 Fax: +61 (0)3 9809 7999
GT	BGP Products Pty Ltd 299 Lane Cove Road Macquarie Park NSW 2113 Tel: 1800 225 311
GX	Apotex Pty Ltd 16 Giffnock Avenue MACQUARIE PARK NSW 2113 Tel: 1800 276 839
GZ	sanofi-aventis Australia Pty Ltd Building D, Talavera Corporate Centre 12-24 Talavera Road Macquarie Park NSW 2113 Tel: +61 (0)2 8666 2000
HB	Besins Healthcare Australia Pty Ltd Level 20, Tower A, The Zenith 821 Pacific Highway Chatswood NSW 2067 Tel: +61 (0)2 9418 8343

Code	Manufacturer
HH	Hospira Pty Limited Level 3 500 Collins Street Melbourne VIC 3000 Tel: 1300 046 774
HL	Helex-A Pty. Ltd. 9/7 Anella Avenue CASTLE HILL NSW 2154 Tel: 1800 824 166
HM	Meda Pharmaceuticals Pty Ltd Suite 1, Level 3 110 Pacific Highway St Leonards NSW 2065 Tel: +61 (0)2 8209 3422 Fax: +61 (0)2 9436 4489
HR	Paul Hartmann Pty Ltd 27-28/11-21 Underwood Road Homebush NSW 2140 Tel: 1800 805 839
HX	Sandoz Pty Ltd Suite 201, Level 2 19 Harris Street Pyrmont NSW 2009 Tel: 1800 726 369
IA	iNova Pharmaceuticals (Australia) Pty Limited Po Box 5033 WEST CHATSWOOD NSW 2067 Tel: +61 (0)2 8918 6322 Fax: +61 (0)2 8918 6415
IB	Apotex Pty Ltd 16 Giffnock Avenue MACQUARIE PARK NSW 2113 Tel: 1800 276 839
IF	Infopia Australia Pty Ltd 160/788 Bourke St Waterloo NSW 2017 Tel: 1800 694 636
IK	Medtronic Australasia Pty Ltd 97 Waterloo Road North Ryde NSW 2113 Tel: 1800 777 808
IQ	Alcon Laboratories (Australia) Pty Ltd 10/25 Frenchs Forest Road East FRENCHS FOREST NSW 2086 Tel: 1800 025 032
IS	Ipsen Pty Ltd Level 2, Building 4 Brandon Office Park GLEN WAVERLEY VIC 3150 Tel: +61 (0)3 8544 8100
IV	iNova Pharmaceuticals (Australia) Pty Limited Po Box 5033 WEST CHATSWOOD NSW 2067 Tel: +61 (0)2 8918 6322 Fax: +61 (0)2 8918 6415

Index of Manufacturers' codes

Code	Manufacturer
IX	Clinect Pty Ltd Level 3, 484 St Kilda Road Melbourne VIC 3004 Tel: (03) 9918 5555
JC	Janssen-Cilag Pty Ltd 1-5 Khartoum Road North Ryde NSW 2113 Tel: +61 (0)2 8875 3333 Fax: +61 (0)2 8875 3300
JJ	Johnson & Johnson Medical Pty Ltd 1-5 Khartoum Road North Ryde NSW 2113 Tel: +61 (0)2 9815 4276
JN	JNS Biomedical Pty Ltd 99 Finlayson Street Rosanna VIC 3084 Tel: +61 (0)3 9913 4660
JT	Johnson & Johnson Pacific Pty Limited 45 Jones street Ultimo NSW 2007 Tel: 1800 029 979
KE	Kendall Australasia Pty Ltd 22 Giffnock Avenue North Ryde NSW 2113 Tel: 1800 252 467
KI	KCI Medical Australia Pty Ltd Level 7, 15 Orion Road Lane Cove West NSW 2066 Tel: 1800 815 529 Fax: +61 (0)2 9422 4344
KP	Eli Lilly Australia Pty Ltd 112 Wharf Road West Ryde NSW 2114 Tel: (02) 9325 4444
KY	Key Pharmaceuticals Pty Ltd 12 Lyon Park Road MACQUARIE PARK NSW 2113 Tel: (02) 8113 6200
LL	Astellas Pharma Australia Pty Ltd Level 4, 6 Eden Park Drive Macquarie Park NSW 2113 Tel: 1800 751 755
LM	Link Medical Products Pty Ltd Unit 1 5 Apollo Street WARRIEWOOD NSW 2102 Tel: +61 (0)2 8401 9777
LN	Aspen Pharmacare Australia Pty Limited 34-36 Chandos Street ST LEONARDS NSW 2065 Tel: (02) 8436 8300
LO	Leo Pharma Pty Ltd Level 3, Tower 1 25 Montpelier Road Bowen Hills QLD 4006 Tel: (07) 32501200

Code	Manufacturer
LS	Astellas Pharma Australia Pty Ltd Level 4, 6 Eden Park Drive Macquarie Park NSW 2113 Tel: 1800 751 755
LU	Lundbeck Australia Pty Ltd Ground Floor 1 Innovation Road NORTH RYDE NSW 2113 Tel: (02) 88691000
LY	Eli Lilly Australia Pty Ltd 112 Wharf Road West Ryde NSW 2114 Tel: (02) 9325 4444
MD	Roche Products Pty Ltd 4-10 Inman Road DEE WHY NSW 2099 Tel: +61 (0)2 9454 9000 Fax: +61 (0)2 9971 7401
MF	Mundipharma Pty Limited 50 Bridge Street SYDNEY NSW 2000 Tel: 02 9231 7200
MH	Molnlycke Health Care Pty Ltd Building 1, Ground Floor 14 Aquatic Drive Frenchs Forest NSW 2086 Tel: +61 (0)2 9453 1144 Fax: +61 (0)2 9453 1155
MK	Merck Sharp & Dohme (Australia) Pty Ltd Level 1, Building A 26 Talavera Road MACQUARIE PARK NSW 2113 Tel: +61 (0)2 8988 8000
MM	3M Pharmaceuticals Australia Pty Ltd 9-15 Chilvers Road Thornleigh NSW 2120 Tel: (02) 9875 6333
MQ	Alphapharm Pty Ltd Level 1 30 The Bond, 30-34 Hickson Rd MILLERS POINT NSW 2000 Tel: 1800 028 365
MS	Abbott Australasia Pty Ltd Sir Joseph Banks Corporate Park 32-34 Lord Street BOTANY NSW 2019 Tel: 1800 801 478
MT	Mentholatum Australasia Pty Ltd 12-16 Janine Street Scoresby VIC 3179 Tel: (03) 9763 0322
MW	Biomed Aust Pty Limited C/o Robinson Legal Level 4, 350 Kent Street SYDNEY NSW 2000 Tel: +61 (0)2 9815 5405

Index of Manufacturers' codes

Code	Manufacturer
NA	National Diagnostic Products (Australia) Pty Limited 7-9 Merriwa Street Gordon NSW 2072 Tel: +61 (0)2 9418 4777 Fax: +61 (0)2 9418 4747
NC	Novartis Consumer Health Australasia Pty Ltd 327-333 Police Road Mulgrave VIC 3170 Tel: 1800 069 643
NE	Norgine Pty Limited Unit 3, 14 Rodborough Road FRENCHS FOREST NSW 2086 Tel: 1800 636 000
NF	Novo Nordisk Pharmaceuticals Pty Limited Level 3, 21 Solent Circuit Baulkham Hills NSW 2153 Tel: (02) 8858 3600
NI	Novo Nordisk Pharmaceuticals Pty Limited Level 3, 21 Solent Circuit Baulkham Hills NSW 2153 Tel: (02) 8858 3600
NJ	Norac Pharma Australia Pty Ltd Suite 401 7 Oaks Avenue DeeWhy NSW 2099 Tel: +61 (0)2 9981 4470
NM	Novartis Pharmaceuticals Australia Pty Limited 54 Waterloo Road North Ryde NSW 2113 Tel: 1800 671 203
NO	Novo Nordisk Pharmaceuticals Pty Limited Level 3, 21 Solent Circuit Baulkham Hills NSW 2153 Tel: (02) 8858 3600
NQ	Takeda Pharmaceuticals Australia Pty Ltd Ground Floor, 2-4 Lyonpark Road MACQUARIE PARK NSW 2113 Tel: +61 (0)2 9859 6900 Fax: +61 (0)2 9859 6950
NT	Nestle Australia Ltd 20-24 Howleys Road Notting Hill VIC 3168 Tel: 1800 025 361
NU	Nutricia Australia Pty Limited Level 4, Building D 12-24 Talavera Road Macquarie Park NSW 2113 Tel: +61 (0)2 8875 0300
NV	Novartis Pharmaceuticals Australia Pty Limited 54 Waterloo Road North Ryde NSW 2113 Tel: 1800 671 203
NX	Nipro Australia Pty Ltd Suite 3, 500 Pacific Hwy ST LEONARDS NSW 2065 Tel: 1800 451 737

Code	Manufacturer
OA	Orphan Australia Pty Ltd First Floor 34-36 Chandos Street ST LEONARDS NSW 2065 Tel: (02) 8436 8300
OB	Oral B Laboratories Pty Ltd Level 3, 90 Mount Street North Sydney NSW 2060 Tel: (02) 9957 6499
OE	Omegapharm Pty Ltd 21 Queen Street ORMOND VIC 3204 Tel: +61 (0)418 351 065
OI	Boian Surgical Pty Ltd 486 King Georges Road BEVERLY HILLS NSW 2209 Tel: (02) 9580 7447
OL	Owen Laboratories Division of Galderma Australia Pty Ltd 9 Rodborough Road Frenchs Forest NSW 2086 Tel: 1800 800 765
OM	Colgate Oral Care 345 George Street Sydney NSW 2000 Tel: (02) 9229 5600
ON	Orion Laboratories Pty Ltd 25-29 Delawney Street Balcatta WA 6021 Tel: 1800 004 110
OZ	Medical Specialties Australia Unit Trust 54 Gibbes Street Chatswood NSW 2067 Tel: (02) 9417 7955
PB	Pharmaco (Australia) Limited Level 1, 170 Fullarton Road Dulwich SA 5065 Tel: 1 800 201 564 Fax: 1 800 603 224
PE	Allergan Australia Pty Limited Level 4, 810 Pacific Highway Gordon NSW 2072 Tel: 1800 252 224
PF	Pfizer Australia Pty Ltd 38-42 Wharf Road West Ryde NSW 2114 Tel: +61 (0)2 9850 3333
PK	Fresenius Kabi Australia Pty Limited 964 Pacific Highway Pymble NSW 2073 Tel: 1800 181 537
PL	The Trustee for Virgo Unit Trust (trading as Phebra) 19 Orion Road Lane Cove West NSW 2066 Tel: 1800 720 020

Index of Manufacturers' codes

Code	Manufacturer
PM	Pharmaceutical Manufacturing Company Pty Limited 5 Alma Road NORTH RYDE NSW 2113 Tel: (02) 9978 3500
PP	Petrus Pharmaceuticals Pty Ltd PO Box 1808 WEST PERTH WA 6872 Tel: +61 (0)8 9368 5954
PQ	PMIP Pty Ltd Unit 1 5 Apollo Street WARRIEWOOD NSW 2102 Tel: +61 (0)2 8401 9777
PX	Point of Care Diagnostics Australia Pty Ltd Unit 14 76 Reserve Road ARTARMON NSW 2064 Tel: (02) 9437 1355
PY	Procter & Gamble Pharmaceuticals Australia Pty Ltd 99 Phillip Street Parramatta NSW 2150 Tel: (02) 9685 4500
QA	Aspen Pharma Pty Ltd 34-36 Chandos Street ST LEONARDS NSW 2065 Tel: (02) 8436 8300
QB	Bionime Australia Pty Limited 75/359 Pitt Street SYDNEY NSW 2000 Tel: (02) 9262 6900
QH	Cortex Health Pty Ltd Suite 3 309 Hampton Street Hampton VIC 3188 Tel: 1800 367 758 Fax: +61 (0)3 8677 7663
QL	Amcla Pty Limited Unit 4/490 Frankston Dandenong Road CARRUM DOWNS VIC 3201 Tel: +61 (0)3 9782 4777
RA	Ranbaxy Australia Pty Limited Ground Floor 9-13 Waterloo Road NORTH RYDE NSW 2113 Tel: +61 (0)2 9887 2600
RB	Bio Revive Pty Ltd 182-184 Stawell St Burnley VIC 3121 Tel: +61 (0)3 8416 0399
RC	Reckitt Benckiser (Australia) Pty Limited 44 Wharf Road WEST RYDE NSW 2114 Tel: 1800226766

Code	Manufacturer
RD	Roche Diagnostics Australia Pty Limited 31 Victoria Avenue CASTLE HILL NSW 2154 Tel: 1800 251 816
RI	Dr Reddy's Laboratories (Australia) Pty Ltd Level 9 492 St Kilda Road Melbourne VIC 3004 Tel: 1800 733 397 Fax: +61 (0)3 9595 3556
RO	Roche Products Pty Ltd 4-10 Inman Road DEE WHY NSW 2099 Tel: +61 (0)2 9454 9000 Fax: +61 (0)2 9971 7401
RX	Servier Laboratories (Aust.) Pty Ltd 8 Cato Street HAWTHORN VIC 3122 Tel: (03) 8823 7333
RZ	Dr Reddy's Laboratories (Australia) Pty Ltd Level 9 492 St Kilda Road Melbourne VIC 3004 Tel: 1800 733 397 Fax: +61 (0)3 9595 3556
SA	SciGen (Australia) Pty Limited Suite 1 13B Narabang Way BELROSE NSW 2085 Tel: 1800 966 303
SB	Nutricia Australia Pty Limited Level 4, Building D 12-24 Talavera Road Macquarie Park NSW 2113 Tel: +61 (0)2 8875 0300
SE	Servier Laboratories (Aust.) Pty Ltd 8 Cato Street HAWTHORN VIC 3122 Tel: (03) 8823 7333
SG	Merck Serono Australia Pty Ltd Unit 3-4, 25 Frenchs Forest Road East Frenchs Forest NSW 2086 Tel: +61 (0)2 8977 4100
SI	Sigma Company Limited 3 Myer Place ROWVILLE VIC 3178 Tel: 03 9215 9215
SJ	Sharpe Laboratories Pty Ltd 12 Hope Street Melrose Park NSW 2114 Tel: +61 (0)2 9858 5622
SN	Smith & Nephew Pty Limited 315 Ferntree Gully Road Mount Waverley VIC 3149 Tel: 13 13 60

Index of Manufacturers' codes

Code	Manufacturer
SS	SSL Australia Pty Ltd 225 Beach Road Mordialloc VIC 3195 Tel: 1800 999 155
SW	sanofi-aventis Australia Pty Ltd Building D, Talavera Corporate Centre 12-24 Talavera Road Macquarie Park NSW 2113 Tel: +61 (0)2 8666 2000
SY	Bayer Australia Ltd 875 Pacific Highway Pymble NSW 2073 Tel: 1800 673 270
SZ	Sandoz Pty Ltd Suite 201, Level 2 19 Harris Street Pyrmont NSW 2009 Tel: 1800 726 369
TB	Teva Pharma Australia Pty Limited Level 2, 37 Epping Road Macquarie Park NSW 2113 Tel: +61 (0)2 8061 9900
TK	Takeda Pharmaceuticals Australia Pty Ltd Ground Floor, 2-4 Lyonpark Road MACQUARIE PARK NSW 2113 Tel: +61 (0)2 9859 6900 Fax: +61 (0)2 9859 6950
TL	Tolmar Australia Pty Ltd Building 2, Level 2, Suite 4 20 Bridge Street Pymble NSW 2073 Tel: +61 (0)2 9440 6700
TM	Technipro Marketing Pty Ltd PO Box 38 OATLANDS NSW 2117 Tel: +61 (0)2 9897 5899
TS	Specialised Therapeutics Australia Pty Ltd PO Box 250 EAST KEW VIC 3102 Tel: 1300 798 820
TW	Apotex Pty Ltd 16 Giffnock Avenue MACQUARIE PARK NSW 2113 Tel: 1800 276 839
TX	Apotex Pty Ltd 16 Giffnock Avenue MACQUARIE PARK NSW 2113 Tel: 1800 276 839
UA	Actavis Pty Ltd Level 5, 117 Harrington Street The Rocks NSW 2000 Tel: 1800 678 302
UC	UCB Australia Proprietary Limited Level 1 1155 Malvern Road Malvern VIC 3144 Tel: +61 (0)3 9828 1800

Code	Manufacturer
UH	uHealth Australia Pty Limited 239/117 Old Pittwater Road Brookvale NSW 2100 Tel: 1300 651 478 Fax: 1300 651 378
UM	Unomedical Pty Ltd 11-17 Wilmette Place Mona Vale NSW 2103 Tel: (02) 9997 8033
UN	Unilever Australia Limited 20-22 Cambridge Street Epping NSW 2121 Tel: 1800 888 449
VE	AbbVie Pty Ltd Level 7 241 O'Riordan Street Mascot NSW 2020 Tel: 1800 043 460
VF	Vitaflo Australia Pty Limited 1/110 Balliang Street SOUTH GEELONG VIC 3220 Tel: +61 (0)3 5229 8222
VI	ViiV Healthcare Pty Ltd Level 4 436 Johnston Street Abbotsford VIC 3067 Tel: +61 (0)3 9721 6000
VL	Vifor Pharma Pty Limited Level 8 80 Dorcas Street Southbank VIC 3006 Tel: +61 (0)3 9686 0111 Fax: +61 (0)3 9686 0333
VN	Actavis Pty Ltd Level 5, 117 Harrington Street The Rocks NSW 2000 Tel: 1800 678 302
VR	Vertex Pharmaceuticals (Australia) Pty Ltd Level 32 101 Miller Street North Sydney NSW 2060 Tel: 1800 179 987
WA	sanofi-aventis Australia Pty Ltd Building D, Talavera Corporate Centre 12-24 Talavera Road Macquarie Park NSW 2113 Tel: +61 (0)2 8666 2000
WI	Wincot Pty Limited 74 Balgownie Drive Armidale NSW 2350 Tel: +61 (0)2 6772 5855
XA	Pharmaxis Ltd 20 Rodborough Road FRENCHS FOREST NSW 2086 Tel: (02) 9454 7200

Index of Manufacturers' codes

Code	Manufacturer
XH	MS Health Pty Ltd Suite 129 135 Cardigan Street Carlton VIC 3053 Tel: 1300 515 883 Fax: +61 (0)3 9658 7449
XI	Alexion Pharmaceuticals Australasia Pty Ltd Suite 226-227 117 Old Pittwater Road Brookvale NSW 2100 Tel: +61 (0)2 9091 0500 Fax: +61 (0)2 9091 0511
XM	The Medicines Company (Australia) Pty Limited Suite 1 Level 8, North Tower, 1-5 Railway Street CHATSWOOD NSW 2067 Tel: 1800 755 459
YN	Mayne Pharma International Pty Ltd Level 14 474 Flinders Street MELBOURNE VIC 3000 Tel: 1300 081 849

Code	Manufacturer
YT	Mayne Products Pty Ltd Level 14 474 Flinders Street MELBOURNE VIC 3000 Tel: 1300 081 849
ZF	Sun Pharmaceutical Industries (Australia) Pty Ltd 1053 Burwood Highway FERNTREE GULLY VIC 3156 Tel: (03) 95686102
ZI	Shire Australia Pty Limited Avaya House Level 6, 123 Epping Road North Ryde NSW 2113 Tel: 1800 012 612
ZP	Medis Pharma Pty Ltd L3, 5 Essex St, The Rocks Sydney NSW 2000 Tel: +61 (0)2 8220 4650 Fax: +61 (0)2 9251 1099
ZX	Zenex Pharmaceuticals Pty Ltd 21 Mutimer Street Preston VIC 3072 Tel: +61 (0)4 1378 2370

Section 1 — Explanatory Notes

Introduction

These Explanatory Notes are provided to help PBS prescribers and pharmacists work within the Australian Government's Pharmaceutical Benefits Scheme (PBS).

The PBS is a system of subsidising the cost of most prescription medicines. The subsidies are available to all Australian residents and eligible foreign visitors, i.e., people from countries which have Reciprocal Health Care Agreements with Australia. These countries are the United Kingdom, Ireland, New Zealand, Malta, Italy, Sweden, the Netherlands, Finland, Norway, Belgium and Slovenia.

The aim of the PBS, which has been in operation since 1948, is to provide reliable and affordable access to a wide range of necessary medicines.

The Schedule of Pharmaceutical Benefits referred to throughout as the 'Schedule' – lists all the medicinal products available under the PBS, and explains the uses for which they can be subsidised.

The Schedule is produced monthly by the Australian Department of Health (effective on the first day of each month).

It is vital therefore that PBS prescribers and pharmacists remain up to date with information on which medicines are included in or excluded from the Schedule, which PBS prescribers may prescribe certain medicines, whether restrictions apply to the medicines, and how much patients should pay.

Queries relating to the PBS can be made to the Pharmaceutical Benefits Branch of the Department of Human Services (telephone 132 290 open 24 hours a day, 7 days a week). Queries relating to the Repatriation Pharmaceutical Benefits Scheme (RPBS) can be made to the State offices of the Department of Veterans' Affairs (DVA) (telephone 1800 552 580).

1. The Schedule — Where to Find What

The Schedule of Pharmaceutical Benefits is divided into sections. At the start of the Schedule, immediately after the table of contents, is a summary of any changes to listed items. This is followed by a list of important information sources, contacts and addresses, then an index of manufacturers' codes.

The last pages of the Schedule provide a generic/proprietary index of PBS and RPBS ready-prepared items.

Section 1

Section 1 is what you are reading, the Explanatory Notes. It outlines the correct way to prescribe and supply pharmaceutical benefits; patient charges; who qualifies for concessions; how the Safety Net system works; and, for pharmacists, how to claim reimbursement for PBS items.

Please note that except where indicated, the term '**prescriber**' is used in this section to cover doctors, dentists, optometrists, midwives and nurse practitioners who are approved to prescribe PBS medicines under the National Health Act 1953.

And except where stated otherwise, the term '**pharmacist**' means a pharmacist approved to supply medicines under the PBS.

Section 2

This section lists ready-prepared items, and includes the form, manner of administration, brand and brand equivalents which may be prescribed, and the maximum quantity and number of repeats for each item.

Prescriber bag supplies are also listed at the beginning of this section.

Medicines that have restrictions on how they can be prescribed are printed in ***bold italics***. Items appearing in more than one therapeutic group are cross-referenced.

The second page of Section 2 explains symbols used throughout the Schedule.

The use of 'NOTE' in this section is used to clarify how some pharmaceutical benefits should be prescribed.

The use of 'CAUTION' is to warn of known adverse reactions from, or precautions to be taken with, a particular pharmaceutical benefit. (The absence of a cautionary note does not imply reactions may not happen.)

Separate lists at the end of Section 2 relate to items that can be prescribed by dentists and optometrists who work within the PBS. These are followed by a list of items that are made available under special arrangements for doctors to prescribe.

Section 3

This section lists container prices, fees related to dispensing, standard packs and prices for ready-prepared preparations.

Section 4

This section deals with extemporaneous preparations. It lists the ingredients which can be used, a table of maximum quantities and number of repeats, container prices, and a list of standard formula preparations and prices (based on formularies in common use and referred to in the Schedule as the Standard Formulae List).

Restrictions applying to the use of a pharmaceutical benefit are indicated against the item.

Repatriation Schedule of Pharmaceutical Benefits

After Section 4, the Schedule provides information about pharmaceutical benefits under the RPBS. These may only be prescribed to DVA beneficiaries holding one of the repatriation health cards (see details under '4. Patient Charges').

2. Prescribing Medicines – Information for PBS Prescribers

PBS prescribers

Pharmaceutical benefits can only be prescribed by doctors, dentists, optometrists, midwives and nurse practitioners who are approved to prescribe PBS medicines under the *National Health Act 1953*.

There are separate arrangements for PBS prescriptions in certain public hospitals. To gain access to pharmaceutical benefits under this arrangement a patient must attend a participating public hospital and be a discharge patient or non-admitted patient. Only a medical practitioner providing medical treatment or a midwife providing midwifery treatment or a nurse practitioner providing nurse practitioner treatment within a participating public hospital may prescribe PBS subsidised medication from a hospital. The States of Victoria, Queensland, South Australia, Western Australia and Tasmania, and the Northern Territory have agreed to implement these arrangements.

PBS Prescription forms

Standard PBS prescription forms are available from the Department of Human Services for prescribing pharmaceutical benefits.

For doctors:

- *Personalised forms* — are printed with the doctor's name, qualifications, practice address/es, telephone number and prescriber number (which relates to pharmaceutical benefits). They are only provided to doctors who have a Medicare provider number.
- *Non-personalised (blank) forms* — are distributed as an emergency supply (usually when a doctor has temporarily run out of personalised forms).
- *Locum forms* — have the doctor's name, prescriber number and telephone number (if available) and a space to record the practice where the doctor is working.
- *PBS/RPBS Authority Prescription Forms* — can be in personalised, non-personalised or locum format.
- *Computer PBS prescription forms* — are either continuous or single sheet. On the reverse side they list the name, address and telephone number of the practice, and in the case of a sole doctor practice, the doctor's name.

For dentists:

- *Personalised forms* — have the dentist's name, qualifications, practice address/es, telephone number and prescriber number.
- *Non-personalised (blank) forms* — are distributed for emergency supply only.

For optometrists:

- *Personalised forms* — have the optometrist's name, qualifications, practice address/es, telephone number and prescriber number. These forms can be also be used to prescribe authority-required PBS/RPBS items.

For midwives:

- *Personalised forms* — have the midwife's name, qualifications, practice address/es, telephone number and prescriber number.
- *Non-personalised (blank) forms* — are distributed for emergency supply only.

For nurse practitioners:

- *Personalised forms* — have the nurse practitioner's name, qualifications, practice address/es, telephone number and prescriber number.
- *Non-personalised (blank) forms* — are distributed for emergency supply only.

PBS prescription forms for PBS prescribers are supplied free of charge.

The inclusion of the prescriber number on a PBS prescription enables the pharmacist to be sure the prescription is from a legitimate prescriber and satisfies State/Territory legislation. A PBS prescription written by a dentist, an optometrist, a midwife or a nurse practitioner must include the person's approval number as a PBS prescriber.

PBS prescriptions should be provided to the patient in duplicate, as both parts make up a valid PBS prescription. The patient should be reminded to present both the original and the duplicate copy to the pharmacist.

PBS stationery order forms

Prescribers are asked not to over order. Getting the right amount of forms helps to reduce the cost to taxpayers and helps to reduce paper wastage. Also, the pads may deteriorate if stored over time.

Prescribers can gain access to order forms for standard and authority prescription forms as well as computer prescription forms by downloading the required order form from the Department of Human Services website at www.humanservices.gov.au.

The completed order form should be posted to:

Prescription Pad Order Clerk
Pharmaceutical Branch
Department of Human Services
GPO Box 9826
Sydney NSW 2001
Telephone (02) 9895 3295

Preparing general PBS prescriptions

Do's and Don't's

A PBS prescription is only valid when it is written by a doctor, a dentist, an optometrist, a midwife or a nurse practitioner.

The PBS prescription must be for the treatment of the person named on the PBS prescription. A PBS prescription may only be written for the treatment of one person.

A prescriber cannot write more than one PBS prescription for the same pharmaceutical benefit for the same person on the same day.

Up to **three** pharmaceutical benefit items may be included on a single PBS prescription form except for Authority required, Authority required (STREAMLINED) items and optometrist items. These items must be written on individual forms. Pharmaceutical benefits and non-pharmaceutical benefits should not be listed together on the one PBS prescription form.

If an item has a particular manner of administration it may not, as a pharmaceutical benefit, be administered in any other way, e.g., an ophthalmic preparation may not be prescribed for topical use.

If an item is restricted, and the use for the patient is different from the use specified in the restriction, it cannot be prescribed as a pharmaceutical benefit. The prescriber should write the prescription as a non-PBS private prescription. If a standard PBS prescription form is used for this purpose the 'PBS/RPBS' text must be clearly struck out. It should also be endorsed 'non-PBS'.

Prescribers must heed State/Territory laws when prescribing drugs listed as narcotic, specified or restricted in the poisons legislation of the particular State or Territory. Legislative requirements in some States/Territories are such that prescribers may be required to prescribe a drug of addiction on a separate PBS prescription. Prescribers must ensure that prescriptions written under the PBS fall within the limits of the prescribing approval granted to the person under State or Territory requirements. It is the prescriber's responsibility to ensure that PBS prescriptions comply with all aspects of his/her prescriber approval. Inclusion of a PBS medicine for prescribing does NOT confer approval for a particular prescriber to prescribe that medicine if it is not authorised to be prescribed in a particular State or Territory.

A PBS prescriber cannot prescribe a narcotic drug for him/herself.

Prescribers are issued with individual PBS prescription pads by the Department of Human Services for their own use — these pads should not be used by other prescribers.

Doctors should, and dentists and optometrists, midwives and nurse practitioners are required to, include their prescriber number on non-personalised PBS prescriptions.

The following admixtures are not pharmaceutical benefits:

- the admixture of two or more ready-prepared items listed in the Schedule; or
- the admixture of a ready-prepared item and one or more extemporaneous drugs listed in Section 4 of the Schedule; or
- the admixture of a non-pharmaceutical benefit item with a pharmaceutical benefit item.

Writing the PBS prescription

The following rules apply for writing PBS prescriptions:

- they must be written in indelible form (i.e., ink or ball-point pen) in the prescriber's own handwriting (exceptions must be approved by Chief Executive Medicare) either on the standard PBS prescription, or on paper approximately 18 cm x 12 cm, or they can be generated by computer on a form approved by the Department of Human Services. For patient safety reasons, both the original and the duplicate must be legible;
- they must record the prescriber's name and address (and, in the case of dentists, optometrists, midwives and nurse practitioners, the prescriber number), the patient's name, address and entitlement status, and whether the prescription is under the PBS or RPBS;

- they should completely identify the pharmaceutical benefit by detailing the item, dose, form, strength, quantity and instructions for use;
- they should indicate where brand substitution is not permitted. PBS prescriptions must not be prepared using a computer prescribing program that contains a default which would result in all prescriptions being indicated as Brand Substitution Not Permitted; and
- they must be signed by the prescriber and dated. Forward or back dating is not permitted.

Restrictions

Pharmaceutical benefits listed in the Schedule fall into three broad categories:

Unrestricted benefits - have no restrictions on their therapeutic uses;

Restricted benefits - can only be prescribed for specific therapeutic uses (noted as Restricted benefit); and

Authority required benefits - Authority required benefits fall into two categories:

- *Authority required benefits* are restricted benefits that require prior approval from the Department of Human Services or the DVA (noted as **Authority required**)
- *Authority required (STREAMLINED) benefits* are restricted benefits that do not require prior approval from the Department of Human Services or the DVA but require the recording of a streamlined authority code (noted as **Authority required (STREAMLINED)**).

Authority PBS prescriptions

Authority required benefits fall into two categories - *Authority required* and *Authority required (STREAMLINED)*.

All PBS prescribers (with the exception of dentists) can write authority PBS prescriptions.

Authority PBS prescriptions cannot have retrospective approval.

Authority required PBS Prescriptions

Approval of authority PBS prescriptions by Chief Executive may be sought by:

- posting an Authority Prescription Form to the Department of Human Services - after approval, the Department of Human Services will forward both copies of the prescription to the patient or the prescriber (if it is to be sent direct to the patient, the prescriber should mark the box next to the patient's details);
- calling the Department of Human Services Telephone Authority Applications Freecall service (1800 888 333); or
- using the Department of Human Services PBS authorities website at www.medicareaustralia.gov.au/provider/pbs/doctor/authorities.jsp.

Approval of authority prescriptions by the DVA may be obtained either by posting an Authority Prescription Form to the DVA, or by using the DVA Authority Freecall service (1800 552 580).

An authority PBS/RPBS prescription is not valid until it has been approved by the Department of Human Services or the DVA. Without this approval, a pharmacist must not supply the item as a PBS/RPBS benefit.

Each Authority required PBS/RPBS item must be written on an Authority PBS/RPBS prescription form, one item per form. Authority PBS prescription forms provide for the following:

- the patient/pharmacist copy, which records prescriber, patient, and pharmaceutical benefit item details. Where required a repeat authorisation, which is used for repeat supply, is attached to the pharmacist/patient copy until the last supply is made. The patient/pharmacist copy is then retained by the pharmacist;
- the Department of Human Services/DVA copy which records prescriber, patient, and pharmaceutical benefit item details. After the first dispensing, the Department of Human Services/DVA copy is forwarded to the Department of Human Services for processing and payment;
- the prescriber's copy (for computer generated scripts, this is the tear off portion at the base of the script) or Prescriber/the Department of Human Services/DVA copy (for handwritten scripts this is the long white copy), is kept by the Department of Human Services or the DVA for record purposes when approval is sought in writing. When approval is by telephone or by the authorities website, the prescriber must keep this copy for 12 months. This copy must record the daily dose, details of the disease, clinical justification for using the item, the patient's age (if the patient is a child) and whether the patient has previously received an authority for this pharmaceutical benefit.

Authority required (STREAMLINED) PBS Prescriptions

Prior approval is not required from the Department of Human Services or DVA to prescribe an Authority required (STREAMLINED) item (except where increased quantities and/or repeats are required). Instead the authority prescription form must include a four digit streamlined authority code.

This code is listed with the corresponding restriction for each Authority required (STREAMLINED) item and the prescriber must write the code on the authority PBS/RPBS prescription form. An authority prescription for an Authority required (STREAMLINED) item is not valid unless the code is included on the prescription form. Without the streamlined authority code, a pharmacist must not supply the item as a PBS benefit.

There are no Authority Required (STREAMLINED) items in the Repatriation Schedule of Pharmaceutical Benefits.

Authority required (STREAMLINED) PBS prescriptions must be written on an Authority PBS/RPBS Prescription Form, this includes:

- the pharmacist/patient copy, which records prescriber, patient, and pharmaceutical benefit item details. The prescription is given directly to the patient to be dispensed at their pharmacy;
- the Department of Human Services/DVA copy which records prescriber, patient, and pharmaceutical benefit item details. After the first dispensing, the Department of Human Services/DVA copy is forwarded to the Department of Human Services for processing and payment;
- the prescriber's copy is kept by the prescriber for 12 months. This copy must record the daily dose, details of the disease, clinical justification for using the item, the patient's age (if the patient is a child) and whether the patient has previously received an authority for this pharmaceutical benefit.

Writing authority PBS prescriptions

The following rules apply:

- only one item may be prescribed per PBS prescription;
- PBS prescriptions must be completed by prescribers in writing, unless otherwise approved by the Department of Human Services;
- prescribers should include their name, address, telephone number and **prescriber number** (not provider number);
- prescribers must include the patient's name, address and entitlement status (i.e. whether they are a 'concessional' or 'general patient');
- prescribers must indicate when brand substitution is not permitted. PBS prescriptions must not be prepared using a computer prescribing program that contains a default which would result in all PBS prescriptions being indicated as Brand Substitution Not Permitted;
- in certain circumstances, the prescriber must provide additional information to the Department of Human Services with the authority application; and
- the PBS prescription must be signed by the prescriber and dated.

Posted applications which lack necessary information, and therefore cannot be approved, will be returned for correction. If the matter can be clarified via telephone, an Authority to Prescribe Form may be prepared by the Department of Human Services or the DVA and sent to the prescriber.

In the case of authority PBS prescriptions approved by telephone, the approval number must be included on the PBS prescription to enable the pharmacist to supply the medication. A prescriber who is granted approval but decides not to continue with the therapy should advise the Department of Human Services.

In the case of Authority required (STREAMLINED) prescriptions, the streamlined authority code must be written on the PBS/RPBS prescription form. This enables the pharmacist to supply the medication as a PBS benefit.

Maximum quantities and repeats

The maximum quantity and number of repeats allowed for PBS items are recommended by the Pharmaceutical Benefits Advisory Committee (PBAC). In the case of RPBS items, the recommendations are made by the Repatriation Pharmaceutical Reference Committee (RPRC).

There are no repeats included in PBS listings for items for prescribing by dentists.

PBS prescriptions and repeats can be for any quantity up to the maximum. It is not necessary to prescribe the maximum quantity if a lesser quantity is sufficient for the patient's needs. Please clearly indicate the number of tablets, capsules, etc. required and the number of repeats needed, and **do not use** abbreviations such as 'Max. Qty', 'M.Q.', or 'M.R.'.

If a prescriber feels the maximum quantity or number of repeats should be increased for a particular patient, he or she must complete an Authority PBS Prescription Form (see procedures above under 'Authority PBS Prescriptions'). The provision of increased quantities and repeats on authority PBS prescriptions is intended to provide approximately one month's therapy which may be repeated (if clinically appropriate) to provide 6 months' therapy in total. This situation usually arises where higher than normal dosages are required.

Approval for increased quantities and repeats of Authority required, Authority required (STREAMLINED) and Restricted benefit PBS items will be granted only where the reason for the PBS prescription is consistent with the indications published in the Schedule.

Approval for increased quantities and repeats extends only to the provision of a pharmaceutical benefit for the patient and does not imply approval of any aspects of the patient's care, which are the responsibility of the treating prescriber.

Regulation 24

Under this regulation, original and repeat supplies of pharmaceutical benefits can be supplied at the one time if a medical practitioner, a midwife or a nurse practitioner is first satisfied that certain conditions apply, then endorses the PBS prescription 'Regulation 24'. RPBS prescriptions may be endorsed 'hardship conditions apply'.

The medical practitioner, midwife or nurse practitioner must first be satisfied all the following conditions apply:

- the maximum PBS quantity is insufficient for the patient's treatment; **AND**
- the patient has a chronic illness or lives in a remote area where access to PBS supplies is limited; **AND**
- the patient would suffer great hardship trying to get the pharmaceutical benefit on separate occasions.

Regulation 24 does not apply for supply of pharmaceutical benefits on optometrist prescriptions.

Urgent cases

In urgent cases and where State/Territory law allows, a prescriber may telephone a pharmacist and ask that a PBS prescription be supplied. He/she must then forward the written PBS prescription and duplicate to the pharmacist within **seven days of the date of supply**.

This also applies to 'Authority required' authority PBS prescriptions provided prior approval has been given by the Department of Human Services or DVA. The follow-up written PBS prescription must include the approval number provided over the phone by the Department of Human Services or DVA.

Drugs of addiction

Prescribers must heed State/Territory laws when prescribing drugs listed as narcotic, specified or restricted and must notify, or receive approval from, the appropriate health authority.

When a PBS/RPBS authority application is for a drug of addiction (other than dexamphetamine sulfate), the following guidelines apply:

- the maximum quantity authorised is generally for one month's therapy (e.g., one week's therapy with three repeats);
- where supply for a longer period is warranted, quantities are usually for up to three months' therapy;
- telephone approvals are limited to one month's therapy.

Prescribers should also state the interval of repeat where repeats are called for, and ensure State/Territory health authorities are notified about ongoing treatment.

Prescriber bag supplies

Certain pharmaceutical benefits are provided without charge to prescribers who in turn can supply them free to patients for immediate administration or emergency use.

A drug or a pharmaceutical benefit (as a particular form of a drug), may be available for general prescribing and prescriber bag supply, or via prescriber bag provisions only (ie. not for prescribing as a general pharmaceutical benefit). Prescriber bag items are listed according to the PBS prescribers who may obtain and supply them, and may be listed for one or more PBS prescriber types.

To obtain supplies, a prescriber bag supply order form must be completed in triplicate, signed, and the original and duplicate given to a pharmacist. Each form is valid for the month indicated on the form.

Prescribers may order up to the maximum quantity of an item provided they do not already have the maximum quantity on hand. No more than the maximum quantity can be obtained in a calendar month. Prescribers may order a particular brand of a pharmaceutical benefit. A change to specify another listed brand must be initialised by the prescriber.

A receipt must be signed by the prescriber, or by an authorised representative, when supplies are received.

Improving the capacity of the PBS to meet particular Aboriginal and Torres Strait Islander health needs

The PBS includes listings to support the treatment of conditions common in Aboriginal and Torres Strait Islander health settings. These listings are specifically for your patients who identify as Aboriginal and/or Torres Strait Islander persons. Some listings will be medicines recently added to the PBS; others may contain specific restrictions for existing PBS items.

More information is available on the Factsheet: Listings on the PBS for Aboriginal and Torres Strait Islander people

A significant proportion of the higher levels of illness experienced by Aboriginal and Torres Strait Islanders may be addressed through better access to appropriate medicines. The PBS aims to provide greater choice in therapeutic options and to address:

- the greater burden of disease experienced by Aboriginal and Torres Strait Islander peoples; and
- morbidity almost exclusively seen in this population.

How to prescribe these items?

These items are available as "Authority PBS prescriptions". You should obtain approval from the Department of Human Services before prescribing these items for patients who identify as Aboriginal and/or Torres Strait Islander persons through the Authority Freecall service [1800 888 333], on line or by mail.

All PBS prescribers except dentists can write Authority PBS prescriptions and your patients will be required to pay their normal PBS co-payment.

Special arrangements apply in remote area Aboriginal Health Services for supplying these PBS items.

Aboriginal and Torres Strait Islander identification

Establishing a client's background may have clinical significance and should be part of routine medical history taking. In the case of Aboriginal and Torres Strait Islander people, this is also relevant to establish eligibility for services such as health checks, specific immunisation programs, and the some PBS items.

Improving the level of identification of Aboriginal and Torres Strait Islander people will also assist in developing initiatives to meet particular needs.

For the purposes of these PBS items a person is Aboriginal and/or Torres Strait Islander if the person identifies himself or herself as being an Aboriginal and/or Torres Strait Islander. Clients should be asked to self-identify either verbally or by completing a form.

- Some people may give this information without being asked.
- It is important not to assume that a person is or is not Aboriginal or Torres Strait Islander.

Asking about Aboriginal and/or Torres Strait Islander identification

Practitioners should ensure that each person attending their practice has the opportunity to identify if they are Aboriginal or Torres Strait Islander. An environment which maintains confidentiality and provides an explanation for this question if requested will assist this process.

- The inquiry may be made verbally and recorded by the general practitioner as part of routine medical history taking at first consultation, or by a receptionist or other staff member. An appropriate question to ask is:
"Are you (is this child) of Aboriginal or Torres Strait Islander origin?"
- Alternatively, the question may be included on a client self-history or practice record form, using a standard question such as:
"Are you (is this child) of Aboriginal or Torres Strait Islander origin?"
 - Yes - Aboriginal
 - Yes - Torres Strait Islander
 - Yes - Aboriginal and Torres Strait Islander
 - No

Aboriginal and Torres Strait Islander health

Major causes of excess mortality in Aboriginal and Torres Strait Islander peoples are:

- circulatory conditions (including ischaemic heart disease, hypertension, cerebrovascular disease and rheumatic heart disease);
- external causes (including accident and injury);
- endocrine causes (mainly type two diabetes and its complications); and
- respiratory conditions.

Causes of morbidity vary but include the risk factors and precursors of all of these. They also include infections of the respiratory system, the ears (in particular, chronic suppurative otitis media), the eyes (trachoma in some settings), the skin and the gastrointestinal system. End-stage renal disease is a major cause of hospitalisations, and much early renal disease remains undetected. In some settings, sexually transmissible infections are common.

Living environments affect health and may be compromised by overcrowding, limited access to clean water and sanitation, and poverty. Social and family life may be negatively influenced by an excessive burden of care for family members, by substance use and sometimes by family violence.

Communication and cultural issues

Aboriginal cultures are numerous and diverse in language, customs, non-verbal and verbal communication, geographical locations and experiences. Torres Strait Islanders are a separate people with a distinctly different culture and identity. Aboriginal and Torres Strait Islander people often perceive health differently from other Australians.

For Aboriginal and Torres Strait Islander peoples' health does not just entail the freedom of the individual from sickness but requires support for healthy and interdependent relationships between families, communities, land, sea and spirit. The focus must be on spiritual, cultural, emotional and social well-being as well as physical health

Source: National Aboriginal and Torres Strait Islander Health Council. National Strategic Framework for Aboriginal and Torres Strait Islander Health 2003-2013, Context. Canberra: Commonwealth of Australia; 2004.

To provide effective primary health care to Aboriginal and Torres Strait Islander clients, you need to be aware of the issues surrounding this diversity, and which may have an impact on the delivery of services.

- Aboriginal and Torres Strait Islander people may be reluctant to use mainstream medical services. This may be because of a lack of understanding of the mainstream health system and previous negative experiences within the mainstream health care system.
- Access to adequate health care may be hindered by family obligations (often extended family), lack of transport or money, or geographical isolation.
- English may be the person's second, third or even fourth language. Therefore it may be appropriate to consider the use of an interpreter.
- Aboriginal and Torres Strait Islander people may be reluctant to consult a health care provider of the opposite sex, particularly with regard to women's and men's health issues.

The differences between the cultural and language backgrounds of health service providers and patients, whether urban, rural or remote, may range from minor to extreme.

You should:

- Make efforts to ensure waiting rooms are welcoming to Aboriginal and Torres Strait Islander people, including displaying relevant posters and pamphlets;
- Provide a relaxed setting for the consultation (e.g. sit next to your patient rather than across a desk);
- Allow time at the first consultation to build rapport and trust;

- Ensure the person understands clearly what the service entails and the details of any procedures involved, and possible follow-up or referral requirements;
- Obtain health promotion information appropriate for Aboriginal and Torres Strait Islander patients;
- Allow the patient to have family members present if desired. When inviting family or community members to accompany a patient, ensure the patient fully consents to their attendance and that the community/family members are fully aware of the need for confidentiality;
- Provide gender appropriate staff where possible, for both male and female patients, especially in regard to pap smears, mammograms, sexual health checks, pregnancy checks, antenatal care and postnatal care;
- Encourage all staff in the practice to attend Aboriginal and Torres Strait Islander Cultural Awareness programs, which are widely available;
- Ensure practice staff have awareness of appropriate referral and/or support organisations for Aboriginal and Torres Strait Islander patients; and
- Develop partnerships with local Aboriginal and Torres Strait Islander community organisations.

For more information, pbs-indigenous@health.gov.au

3. Supplying Medicines — What Pharmacists Need to Know

Eligible suppliers

Pharmaceutical benefits are mainly supplied by approved pharmacists – pharmacists who comply with certain conditions. These pharmacists are approved to dispense pharmaceutical benefits from a particular pharmacy.

Other suppliers include approved doctors (usually practising in isolated areas), Friendly Society pharmacies, and approved hospitals. All suppliers are issued with approval numbers by the Department of Human Services. They should follow the procedures in these Explanatory Notes.

An approved pharmacist may only supply pharmaceutical benefits *at or from* premises for which they have been approved.

Unapproved pharmacists *cannot* supply pharmaceutical benefits.

Conditions of Approval for approved pharmacists

The National Health Act 1953 (the Act) allows for payment of a claim for the supply of a pharmaceutical benefit where the supply has been made at or from premises for which the pharmacist is approved under the Act (approved premises).

The Act also provides that payment to an approved pharmacist for the supply of a pharmaceutical benefit cannot be made if it was supplied at or from unapproved premises, or otherwise than in accordance with a condition of approval.

As part of their approval under section 90 of the Act, all approved pharmacists are subject to certain conditions. These include that the approved pharmacist will:

- not supply to anyone any pharmaceutical benefit that attracts a Commonwealth contribution for free, or for a price that is less than the relevant patient contribution;
- clearly advertise that any offer for free or cut-price medicines does not include pharmaceutical benefits which have a Commonwealth contribution; and
- not pay rebates or refunds of patient contributions.

The Act also allows the Minister to determine any other conditions with which approved pharmacists must comply. These additional conditions are set out in the National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists) Determination 2007 (the Conditions of Approval). The Conditions of Approval require that an approved pharmacist must, amongst other requirements:

- comply with all legal requirements for the practice of pharmacy;
- comply with the Pharmaceutical Society of Australia's Code of Ethics and Professional Practice Standards in their dealings with each individual patient; and
- maintain the currency of his or her pharmaceutical knowledge in accordance with the Pharmaceutical Society of Australia's Competency Standards for Pharmacists in Australia.

From 1 December 2014, a new condition of approval is being introduced which sets out the circumstances which must be met before a claim for payment from the commonwealth for the supply of a Pharmaceutical Benefit can be made.

This new condition requires that an approved pharmacist must not make a claim for payment for the supply of a pharmaceutical benefit unless it was supplied at or from approved premises for the pharmacist.

To assist approved pharmacists in understanding the intention of the proposed new condition of approval the Department has prepared a series of Frequently Asked Questions.

- Frequently Asked Questions – (Word 30 KB)
- Frequently Asked Questions - (PDF 109 KB)

Approved pharmacists should be aware that a breach of a condition of approval may lead the following compliance measures:

- recovery of monies;
- reprimand, suspension or revocation of approval (following referral to the Pharmaceutical Services Committee of Inquiry); and/or
- prosecution for criminal offence under the Act or *Criminal Code*.

Should you have concerns about a potential breach of the Conditions of Approval for approved pharmacists, or any other compliance matter, you can report your concerns to The Australian Government Services Fraud Tip-off Line by calling 131 524 or filling out the Reporting suspected fraud (1980) form.

The Department of Human Services investigates all tip-offs related to payments that may have been made incorrectly. However, the Department is not able to provide complainants with updates due to legislated privacy and secrecy provisions. For more information on how to report your concerns, please visit the Department of Human Services website.

Other requirements for approved pharmacists

A pharmacist approved to supply medicines under the PBS:

- will publicly display a notice setting out the pharmacy's normal trading hours;
- is obliged to supply pharmaceutical benefits at the pharmacy at any hour if a PBS prescription is marked 'urgent' and initialled by the prescriber;
- will keep adequate stocks for the supply of pharmaceutical benefits;
- may be called on by the Department of Human Services to provide details of stocks of pharmaceutical benefits or preparations for pharmaceutical benefits; and
- must keep the duplicates of all old format PBS prescriptions, and the patient/pharmacist copies of all new format PBS prescriptions, with a Commonwealth contribution for at least one year from the date of supply. This includes PBS prescriptions ordering repeats when it is the final supply, and order forms for prescriber bag supplies. Please note that some State/Territory laws require these copies to be kept for longer periods.

Before supplying pharmaceutical benefits

Several steps must be taken before a pharmaceutical benefit is supplied.

Firstly, a pharmacist must endorse the PBS prescription and duplicate with his/her name and approved supplier number.

Secondly, a PBS prescription identifying number must be given to the PBS prescription item on both the PBS prescription and duplicate. Any recognised series of numbers may be used.

If more than one item is on a PBS prescription, a separate identifying number should be allocated to each item.

In the case of a repeat authorisation, the same PBS prescription identifying number(s) must be carried through for each item. A pharmacist must also allocate his/her own identifying number on the repeat authorisation. It must be written alongside the date and place of supply.

Supplying pharmaceutical benefits

Do's and Don'ts

Except in urgent cases (see details under '2. Prescribing Medicines ... Urgent cases'), pharmacists are authorised to supply pharmaceutical benefits only after they receive:

- the pharmacist/patient and the Department of Human Services or DVA copies of a valid PBS prescription which is not more than 12 months old; or
- the pharmacist/patient and the Department of Human Services or DVA copies of an approved authority PBS prescription or an authority to prescribe which is not more than 12 months old; or
- a repeat authorisation attached to a patient/pharmacist PBS prescription not more than 12 months after the date of the original PBS prescription.

A pharmacist must not supply an Authority required (STREAMLINED) item unless the prescriber has written the four digit streamlined authority code on an authority PBS/RPBS prescription.

A pharmaceutical benefit cannot be supplied more times than specified in the PBS prescription.

A pharmacist cannot add to, delete from, or alter a PBS prescription in any other way. However, there may be circumstances where after contacting a prescriber, the pharmacist can clarify the prescriber's intentions and endorse the PBS prescription accordingly.

Once a pharmaceutical benefit has been supplied to a patient, it may not be supplied to that patient again:

- on the same day or within the next 20 days, if it is a benefit (other than an eye preparation) that has five or more repeats allowed in the Schedule; or
- on the same day or within the next four days (e.g., if a pharmaceutical benefit is supplied on a Monday, it cannot be supplied again to that patient until the next Saturday) in the case of other benefits.

Exceptions to this are:

- when a PBS prescription is endorsed with the words 'Regulation 24' or 'hardship conditions apply' (see below under 'Regulation 24'); and
- If a pharmacist believes a repeat supply is needed without delay for the treatment of the person, or a previous supply has been destroyed, lost or stolen. In this case, the pharmacist can provide another supply but must write 'immediate supply necessary' and sign the PBS prescription.

A pharmacist can supply an alternative pharmaceutical benefit without reference to the prescriber, provided that:

- the PBS prescription does not indicate that only the pharmaceutical benefit prescribed is to be supplied (ie substitution is not permitted); and
- the Schedule states that the prescribed benefit and the substitute benefits are equivalent; and
- supply of the substitute benefit does not contravene relevant State/Territory law; and
- the substitute benefit is a listed brand in the Schedule.

Pharmacists must heed State/Territory laws when supplying drugs listed as narcotic, specified or restricted in legislation of the particular State or Territory.

What to do if the Schedule changes

If an item or brand is deleted from the Schedule, it *cannot* be supplied as a pharmaceutical benefit from the date the deletion takes effect – regardless of whether the PBS prescription was written before this date. This includes repeat authorisations. (Special conditions applying to RPBS prescriptions are detailed in the RPBS Explanatory Notes.)

However, if restrictions on the prescribing of a pharmaceutical benefit change, or the maximum quantity or number of repeats is altered in the Schedule, valid PBS prescriptions written before the date of effect of the change *may* still be supplied as pharmaceutical benefits, under the conditions applying at the date of prescribing.

Suspected forgery

Pharmacists should take all reasonable steps to satisfy themselves that all items on a PBS prescription were written by a medical practitioner, a dentist, an optometrist, a midwife or a nurse practitioner.

Regulation 24

This regulation allows pharmacists to supply a pharmaceutical benefit and all of its repeats at the one time.

The PBS prescription must be endorsed by the medical practitioner, midwife or nurse practitioner with the words 'Regulation 24' if it is an item under the PBS, or 'hardship conditions apply' if it is being supplied under the RPBS. (For more information see under `2. Prescribing Medicines ... Regulation 24'). Regulation 24 does not apply for supply of pharmaceutical benefits on optometrist prescriptions.

Repeat authorisations

When a PBS prescription calls for repeat supplies, the pharmacist shall prepare a Repeat Authorisation Form, except when the PBS prescription is marked 'Regulation 24'.

The repeat may be requested on a standard PBS prescription, an authority PBS prescription or an Authority to Prescribe Form, or on an earlier repeat authorisation. In the latter case, it must come with the duplicate PBS prescription, or in the new format, the "patient/pharmacist copy".

Preparing Repeat Authorisation Forms

A Repeat Authorisation Form must show:

- the category of benefit (concession or general) – by placing a cross (x) in the relevant box;
- the patient's name and full address;
- in the case of repeats authorised on authority PBS prescriptions, the authority prescription number;
- details of the original PBS prescription stating the item, form, strength, quantity and directions;
- if substitution has occurred, the name of the brand actually supplied;
- for the first supply, the pharmacy name, address and approval number, the date of the original PBS prescription and the allotted PBS prescription identifying number;
- for subsequent supplies, the pharmacy approval number, and the date and PBS prescription number of the original prescription;
- the number of times the item is to be repeated and the number of times it has been supplied;
- the name and pharmacy approval number of the pharmacist issuing the repeat authorisation; and
- the date of supply.

When a repeat authorisation is prepared for any further repeats or deferred supply, a pharmacist must attach the duplicate copy of an old format PBS prescription, or the patient/pharmacist copy of a new format PBS prescription, and give both to the patient at the time of supply.

Repeat authorisations for deferred supply

When a PBS prescription orders a number of pharmaceutical benefit items, but the patient does not need all of the items at the same time, a separate repeat authorisation for each deferred item must be prepared. The words 'original supply deferred' should be indicated across the relevant item on the original PBS prescription, its duplicate, and on the repeat authorisation.

Deferred items must not be claimed on the original PBS prescription.

The Repeat Authorisation Form when it is used for a deferred supply, is issued in the same way as normal repeat authorisations except that:

- '0' is to be inserted in the space for 'no. of times already dispensed'; and
- if no repeats are ordered, '0' is to be inserted in the space for 'no. of repeats authorised'.

Supplying a benefit on a deferred supply repeat authorisation is to be treated as if it is the first time of supply. If repeats are directed, the normal procedure for repeat authorisations applies. Details of the pharmacy at which the deferred supply was authorised are to be written onto subsequent repeat authorisations.

Authority PBS prescriptions

If a pharmacist is presented with an authority PBS prescription and is not sure if it has been approved, he or she should contact the Department of Human Services. Please note that the Department of Human Services will not provide clinical information.

If the authority PBS/RPBS prescription is for an Authority required (STREAMLINED) item the pharmacist should ensure that the prescriber has written the four digit streamlined authority code on the prescription, this enables the pharmacist to supply the item as a PBS benefit.

The pharmacist is required to include the four digit streamlined authority code on the claim for the PBS dispensing.

Urgent cases

In urgent cases and where State/Territory law allows, pharmacists can supply a pharmaceutical benefit to a person without a PBS prescription, provided details of the prescription are given by the prescriber via telephone or other means. The prescriber must then forward the written PBS prescription and duplicate to the pharmacist within **seven days of the date of supply**.

Where a pharmaceutical benefit needs prior approval from the Department of Human Services or the DVA, the prescriber must obtain approval and then advise the pharmacist of the PBS prescription and approval details. Only an original supply can be provided in this manner, not repeats.

Receipts

A person receiving a pharmaceutical benefit item must sign and date a receipt for it. If the person is not the patient, that person must also endorse the PBS prescription or repeat authorisation with his/her address. A receipt cannot be obtained until supply of the benefit has been made.

If a pharmaceutical benefit has to be sent through the post, by rail, or by other means, and a receipt is not practical, the pharmacist must certify on the PBS prescription or repeat authorisation that the benefit has been supplied, and write the date of supply and details of how it was sent. For example, if a pharmaceutical benefit is mailed to a patient on 1 April 2008, the pharmacist should write: "Certified supplied – mailed to patient 1 April 2008 (name of pharmacist) (signature of pharmacist) (date of certification)".

If an item is supplied in an urgent case, or to a person who cannot read or write, the pharmacist should sign and date a statement on the PBS prescription or repeat authorisation, stating the item has been supplied and the date on which it was supplied, and explaining why there is no receipt. For example, if a pharmaceutical benefit is supplied to a patient with a broken arm on 1 May 2008, the pharmacist should write: "Certified supplied 1 May 2008 – patient has a broken arm and is unable to sign (name of pharmacist) (signature of pharmacist) (date of certification)".

Only the pharmacist approved to supply pharmaceutical benefits can certify supply.

Prescriber bag supplies

Pharmacists may supply certain pharmaceutical benefit items free of charge to a PBS prescriber if they receive a prescriber bag order form in duplicate, signed by the prescriber. Only items listed under prescriber bag provisions for the relevant prescriber type can be supplied to the prescriber.

Pharmacists must be satisfied the form was completed by a PBS prescriber and includes the prescriber's name and address. If a pharmacist does not know the prescriber, he/she should confirm the prescriber's registration or PBS prescriber number and endorse this on the back of the form.

For more information see '2. Prescribing Medicines ... Prescriber bag supplies'.

4. Patient Charges

Type of patient

There are two types of PBS beneficiaries, general patients, who hold a Medicare card and concessional patients who hold a Medicare card and one of the following:

- Pensioner Concession Card
- Commonwealth Seniors Health Card
- Health Care Card
- Repatriation Health Card for All Conditions (gold) — concessional patients under RPBS
- Repatriation Health Card for Specific Conditions (white) — only regarded as concessional patients for RPBS prescriptions unless they hold a separate entitlement from Centrelink, otherwise they are general patients
- Repatriation Pharmaceutical Benefits Card (orange) — concessional patients under RPBS
- Safety Net Concession Card or Safety Net Entitlement Card — issued by the Department of Human Services.

Concessional patients are recognised by public hospitals in all States and Territories apart from South Australia (where DVA beneficiaries are treated as general patients) and New South Wales (where holders of a white DVA card are treated as general patients).

Under the Reciprocal Health Care Agreements, visitors from participating countries (see the introduction of this section for the list of countries) are treated as general patients and do not have concessional entitlements. To receive pharmaceutical benefits these visitors may need to present a temporary Medicare card or their passport. Pharmacists should contact the Department of Human Services if they have enquiries about these arrangements.

Establishing entitlement

PBS prescription forms supplied by the Department of Human Services have spaces provided for details of a patient's entitlement status. Anyone can enter this information, which must include:

- a cross (x) in the appropriate box to indicate the level of patient contribution;
- the complete Medicare number (including individual reference number) or complete Veteran file number on the card; and
- if applicable, the complete concession number on the card.

The person who signs the receipt for pharmaceutical benefits also accepts responsibility for the validity of the entitlement information on the PBS prescription.

All PBS prescriptions must have a Medicare or Veteran file number. All concessional PBS prescriptions must have a concession number. However, it is not necessary for the Medicare or Veteran file number, or the concession number to be endorsed on the PBS prescription if it is included in the electronic prescription details supplied by a pharmacist who is using the Claims Transmission System.

What to charge

Patient contribution

Under the PBS, the maximum cost for a pharmaceutical benefit item at a pharmacy is \$37.70 for general patients and \$6.10 for concessional patients, plus any applicable special patient contribution, brand premium or therapeutic group premium. General patients who have reached the safety net threshold (see details under '5. The Safety Net Scheme') may receive pharmaceutical benefits at the concessional rate, plus any applicable special patient contribution, brand premium or therapeutic group premium.

Patients who have a Safety Net Entitlement Card (see details under '5. The Safety Net Scheme') may receive PBS items free of charge, except for any applicable special patient contribution, brand premium or therapeutic group premium.

The contribution rate for general patients as outpatients at public hospitals in most of Australia is \$30.20. The exceptions are in hospitals participating in the pharmaceutical reforms where they pay the safety net value of an item listed in the Schedule (see details under '5. The Safety Net Scheme'), or up to the general co-payment amount for items not listed in the Schedule. The public hospital pharmaceutical reforms enable participating public hospitals to prescribe and supply pharmaceutical medication from the PBS to outpatients and patients upon discharge. A range of chemotherapy drugs is also available for day-admitted and non-admitted chemotherapy patients.

The contribution rate for concessional patients in all public hospitals is equal to the concessional co-payment amount.

The supply of a pharmaceutical benefit or a Repatriation pharmaceutical benefit to a patient is GST-free. Goods and services tax must not be included in the price charged to a patient for the supply of a PBS or RPBS script.

It is the patient's responsibility to pay any charge lawfully imposed by an approved pharmacist or supply may be refused.

The patient contribution rates are adjusted on 1 January each year in line with inflation.

Patient contributions for early supply of some PBS medicines

Prescriptions for some PBS and RPBS pharmaceutical benefits are not eligible for safety net benefits if re-supplied within 20 days of a supply of the same pharmaceutical benefit for the same person. This is known as the 'Safety Net 20 day rule' and came into effect on 1 January 2006.

Where a prescription is subject to the Safety Net 20 day rules:

- the patient contribution does not count towards the Safety Net, and
- after the Safety Net threshold is reached, the usual patient co-payment amount for the corresponding entitlement level (not the Safety Net amount) applies.

For example: The payment for such a prescription for a patient with a Safety Net Entitlement Card would be the concessional co-payment amount — not free. For a general patient with a Safety Net Concession Card, the usual general co-payment amount would apply — not the concessional amount.

The Safety Net 20 day rule does not apply to PBS/RPBS prescriptions originating from hospitals or day hospital facilities.

Special patient contributions, brand premiums and therapeutic group premiums

A special patient contribution is payable for a pharmaceutical benefit when a supplier will not supply it at the benchmark price. Any extra charge for a higher priced benefit is paid by the patient, together with their usual patient contribution. Other than for bleomycin sulfate (available under the 'Efficient Funding of Chemotherapy - Section 100 Arrangements'), exemptions on medical grounds are available, but must be granted by the Department of Human Services. For RPBS special patient contribution arrangements see the RPBS Explanatory Notes.

Under the brand premium arrangements, reimbursement to pharmacists is based on the lowest-priced brand. Any extra charge for a higher priced brand is paid by the patient, together with their usual patient contribution.

Under the therapeutic group premium arrangements, reimbursement to pharmacists is based on the lowest priced benefit items within identified therapeutic groups. Any extra charge for a higher priced benefit is paid by the patient, together with their usual patient contribution. Exemptions on medical grounds are available, but must be granted by the Department of Human Services.

Special patient contributions, brand premiums and therapeutic group premiums apply to maximum quantities. When a quantity is less than, or — on an authority or 'Regulation 24' PBS prescription — more than, the maximum, the contributions or premiums will be a factor of the maximum quantity, using standard pricing rules.

There are separate arrangements for PBS prescriptions in certain public hospitals. To obtain pharmaceutical benefits under these arrangements a patient must attend a participating public hospital and be a discharge patient or non-admitted patient. Only a medical practitioner providing medical treatment or a midwife providing midwifery treatment or a nurse practitioner providing nurse practitioner treatment in a participating public hospital may prescribe PBS subsidised medication. Victoria, Queensland, South Australia, Western Australia, Tasmania and the Northern Territory have these arrangements.

Increased quantities

Where a prescriber has written an authority PBS prescription for a quantity greater than the maximum, the patient contribution should be made for each supply of the increased maximum quantity.

Regulation 24

For 'Regulation 24' PBS prescriptions, a pharmacist should charge the usual patient contribution for the original and for each repeat quantity needed to make up the total supply (plus any applicable special patient contribution, brand premium or therapeutic group premium, for the original and each repeat quantity in the total supply).

After hours

A pharmacist may charge an extra fee if supplying a PBS item outside normal trading hours. This charge is paid by the patient and does not count towards the safety net.

Delivery

A charge can be added for delivering pharmaceutical benefits from the pharmacy. This charge does not count towards the safety net. For RPBS delivery arrangements refer to the RPBS Explanatory Notes.

5. The Safety Net Scheme

The PBS safety net protects patients and their families requiring a large number of PBS or RPBS items. For the purposes of the scheme, the family includes the person:

- the partner or de facto partner;
- children under the age of 16 who are in the care and control of the person; or
- dependent full-time students under the age of 25.

The scheme requires pharmacists, on request by patients, to record the supply of PBS and RPBS items on prescription record forms. When a patient reaches the Safety Net threshold within a calendar year, they qualify to receive PBS or RPBS items at a cheaper price or free of charge for the rest of that year. Any applicable special patient contributions, brand premiums or therapeutic group premiums must still be met by the patient.

The safety net threshold is reached by accumulating eligible patient contributions for PBS prescriptions supplied through community pharmacies and private hospitals and for out-patient medication supplied by public hospitals.

Pharmaceutical benefits (including authority items) can only be counted towards the safety net threshold when prescribed and supplied according to PBS conditions. A medicine supplied by a pharmacist not approved to supply pharmaceutical benefits cannot count towards the safety net.

Prescriptions for some pharmaceutical benefits are not eligible for safety net arrangements if re-supplied within 20 days of supply of the same item for the same person and the patient contribution cannot count towards the safety net (see also details under '4. Patient Charges' and '7. How Pharmacists Claim Reimbursement'). This does not apply to out-patient medications in public hospitals or to any prescriptions originating from a hospital or day hospital facility.

There are separate arrangements for PBS prescriptions in certain public hospitals. To obtain pharmaceutical benefits under these arrangements a patient must attend a participating public hospital and be a discharge patient or non-admitted patient. Only a medical practitioner providing medical treatment or a midwife providing midwifery treatment or a nurse practitioner providing nurse practitioner treatment in a participating public hospital may prescribe PBS subsidised medication. Victoria, Queensland, South Australia, Western Australia, Tasmania and the Northern Territory have these arrangements.

Safety net thresholds

There are two safety net thresholds. The general patient safety net threshold is currently \$1,453.90. When a person and/or their family's total applicable co-payments reach this amount, they may apply for a safety net concession card and pay the concessional co-payment amount of \$6.10 plus any applicable premium for pharmaceutical benefits for the rest of that calendar year.

The concessional safety net threshold is \$366.00 (this also applies to gold, white or orange card holders under the RPBS). When a patient and/or their family's total applicable co-payments reach this amount, they may apply for a safety net entitlement card and may receive pharmaceutical benefits free of charge (except for any applicable premium) for the rest of that calendar year.

Brand premiums, therapeutic group premiums and special patient contributions do not count towards the safety net thresholds.

The safety net thresholds are adjusted on 1 January each year in line with inflation.

Safety net cross-over arrangements

Some patients and/or members of their families will change between general patient and concessional patient status during a calendar year. Patients should apply for the safety net card appropriate to their status at the time they apply.

Concessional patients who were previously general patients can apply for a safety net entitlement card when they reach the concessional safety net threshold. In this case, any pharmaceutical benefits previously supplied at the general co-payment rate in that calendar year will be counted at the concessional rate per item.

General patients who were previously concessional patients can apply for a safety net concession card when they reach the general safety net threshold. In this case, any pharmaceutical benefits previously supplied at the concessional rate in that calendar year will be counted at the concessional rate per item.

In the case of families where one parent holds a concession card and other family members are general patients, the family can choose to apply for either a safety net entitlement card or a safety net concession card.

To receive a safety net entitlement card, all pharmaceutical benefits (including general pharmaceutical benefits) are counted at the concessional rate per item until the concessional threshold is reached. To receive a safety net concession card, general pharmaceutical benefits are counted at the general co-payment rate per item and concessional pharmaceutical benefits at the concessional rate per item, until the general safety net threshold is reached.

White DVA card holders may either be general or concessional patients (depending on their Centrelink entitlements). If they are receiving treatment for a specific disability accepted by the DVA, they are also supplied with specified items under the RPBS at the concessional rate per item. Therefore, these patients are encouraged to maintain a concessional prescription record form, plus a general prescription record form for items not covered under the RPBS.

White card holders may choose at any time to count contributions made at the general level towards the concessional safety net threshold and receive credits equal to the concessional co-payment amount for each pharmaceutical benefit purchased. Alternatively, white card holders can count contributions at the concessional level towards the general safety net, and receive credits equal to the concessional co-payment amount for each pharmaceutical benefit purchased.

Gold or orange DVA card holders may receive all of their prescription items under the RPBS, and only pay the concessional co-payment amount for each item.

Dependants of white, gold or orange card holders are treated separately and may be either general patients or concessional patients. Their prescriptions may be included in the cross-over arrangements.

Recording PBS prescriptions

There are two types of prescription record forms to record PBS prescription items. A blue form, used for items obtained at community pharmacies and available from community pharmacies, Medicare Service Centres and the Department of Human Services; and a grey form, used by out-patients who pay for items at public hospital pharmacies and available from hospital out-patient departments or the Department of Human Services.

Patients should record their general or concessional status on the prescription record form, enter their Centrelink, DVA and/or Safety Net Concession/Entitlement Card number, and list family members covered. General patients must also record their Medicare number when applying for a safety net concession card.

Details to be entered on the form by the pharmacist are:

- date of supply;
- PBS/RPBS code number of the item (for community pharmacies only);
- the safety net value of the item (for community pharmacies only);
- pharmacist's approval number (for community pharmacies only);
- item identification — medicine code, name of medicine or abbreviation (for public hospitals only);
- hospital charge (for public hospitals only);
- hospital safety net number (for public hospitals only); and
- signature of the authorised person making the entry.

Community pharmacists should record in the 'safety net value' column:

- the patient contribution when it is less than the PBS dispensed price; or
- the safety net value shown in the Schedule, or any lesser amount charged, if the PBS dispensed price is less than or equal to the patient contribution. The pharmacist may discount the price for these items.

Some computer software suppliers provide a special label to record this information on the prescription record forms. Some suppliers also provide a computer printout as a prescription record form.

The patient is responsible for maintenance and storage of their prescription record form. However, it may be kept in the pharmacy. A person (or family) may have more than one prescription record form.

Hospital prescription record forms

Items to be recorded on hospital prescription record forms must be approved by the hospital's pharmaceutical advisory committee and may be listed on a hospital's formulary (a list of pharmaceutical items approved by the committee for the treatment of particular illnesses), or authorised on a patient-by-patient basis.

Multi-item prescription forms

If a patient submits a multi-item PBS prescription form, which would take the total co-payments past the safety net threshold, any items in excess are treated as entitled items once a safety net entitlement/concession card is issued.

Excess items should be treated as 'deferred supply' items.

For example, if a family has a new PBS prescription for three items and the first takes the family up to the threshold, then this item should be supplied at the general rate. If the second item takes the family over the threshold, the pharmacist should then issue a safety net concession card and supply both this and the third item at the concessional rate. This involves the deferral of two items, recording the safety net concession card number, and the subsequent supply of these items.

Qualifying PBS prescriptions

A PBS prescription should be supplied at the concessional rate or free of charge plus any applicable premium, when the safety net value or hospital charge for that PBS prescription takes the total co-payments over the qualifying amount for a safety net entitlement/concession card.

Lost prescription record forms

If a prescription record form has been lost, stolen or destroyed, a pharmacist may prepare a duplicate copy, but is under no obligation to do so.

Retrospective entitlement and patient refunds

Responsibility for claiming entitlements rests with the patient. If items recorded on a prescription record form have exceeded the safety net threshold, the cost of those items in excess of the limit cannot be refunded by a pharmacist.

However, if the patient failed to apply for a safety net entitlement/concession card on reaching the safety net threshold they should write to the Department of Human Services and provide copies of pharmacy accounts or a signed statement from the pharmacist giving the date of supply, description and cost of items supplied and paid for. A copy of the relevant prescription record form should also be provided. If these are not available, the patient should give the name of the pharmacy where the card was issued and the number on the card so that the Department of Human Services can locate the prescription record form in its records. Cash refunds are not available. The Department of Human Services contact details are provided in the 'Addresses — Department of Human Services' part of the Schedule.

If the patient cannot satisfy a pharmacist that they have a current entitlement and is charged the general patient price, the pharmacist should issue the patient with a receipt and a claim form (provided by the Department of Human Services). The patient can then obtain a refund via Medicare Service Centres or PBS processing centres. RPBs prescription refunds are paid at DVA State offices.

The Department of Human Services can only pay refunds for PBS items supplied through approved pharmacies. Refunds for hospital supplied items should be referred to the relevant hospital or health department. Refunds cannot be made where the patient was charged the general or concessional amount instead of the safety net concessional or safety net entitlement amount as a result of the safety net 20 day rule. Receipts for prescriptions where the safety net 20 day rule has applied must include 'SN20DR' to indicate the reason for the amount charged.

There are separate arrangements for PBS prescriptions in some public hospitals. To obtain pharmaceutical benefits under these arrangements a patient must attend a participating public hospital and be a discharge patient or non-admitted patient. Only a medical practitioner providing medical treatment or a midwife providing midwifery treatment or a nurse practitioner providing nurse practitioner treatment in a participating public hospital may prescribe PBS subsidised medication. Victoria, Queensland, South Australia, Western Australia, Tasmania and the Northern Territory have these arrangements.

Applying for a Safety Net Entitlement/Concession Card

Once the safety net threshold has been reached, the person covered by a prescription record form may complete the application and declaration to get a safety net entitlement/concession card. Please note that software packages that produce computer generated applications must be approved by the Department of Human Services.

If the card is issued to a dependent child or student, it should be in the name of a parent.

When issuing entitlement/concession cards, pharmacists do not have to check all prescription record form details. However, they should ensure each entry has been signed and that the prescription record form total qualifies the patient for the relevant safety net card.

When appropriate the pharmacist should check that the patient's Medicare card number is on the prescription record form.

Issuing a Safety Net Entitlement/Concession Card

When satisfied that the individual or family is entitled, the pharmacist should issue the next blank safety net entitlement/concession card with the following details:

- the names of family members covered. If there are more than eight family members, a second card should be issued listing the card holder and family members not listed on the first card. The prescription record form has space to record that two cards have been issued, and
- the two-character code to indicate the relationship to the card holder. Applicable codes are:
 - SP - partner;
 - DC - child under 16 years; and
 - DS - dependent full-time student under 25 years.

The pharmacist should be satisfied that only family members are listed on the card. The unused space on the card should be ruled through to prevent extra names being added. The sticky label from the safety net entitlement/concession card, pre-printed with the card number, should be attached to the prescription record form. The pharmacist should sign and stamp each prescription record form with the pharmacy stamp and enter the card issue details on a safety net — claim for payment form.

Issuing supplementary cards

A pharmacist may give a card holder a supplementary card for a partner or dependant only at the time the original card is issued. The duplicate card should be recorded in the additional box on the prescription record form.

Later requests for supplementary cards and requests to add a new family member to the original card are to be referred to the Department of Human Services.

Notification to the Department of Human Services and claim for payment

Payment for issuing a safety net entitlement/concession card is made after the safety net — claim for payment form is sent to the Department of Human Services, no later than one month after a card is issued.

Each form must be accompanied by all supporting documentation (prescription record form and cancelled or void safety net entitlement/concession cards).

Payment will not be made for void cards.

Lost Safety Net Entitlement/Concession Cards

When a card has been lost, damaged, stolen or destroyed, a pharmacist cannot re-issue a person with a replacement card. The original card holder (or partner) must apply to the Department of Human Services.

Pharmacy record of issued cards

A record of all cards issued must be kept at the pharmacy from which the pharmacist is approved to supply pharmaceutical benefits. The duplicate ('bookfast') copy in the safety net — claim for payment book is provided for this purpose.

6. Department of Human Services Entitlement Checks

General Patients

The Department of Human Services validates a patient's entitlement to pharmaceutical benefits by checking the Department of Human Services and/or Veteran file numbers in pharmacist's claims. If a number is not recorded correctly, a patient cannot be identified against the Department of Human Services' Pharmaceutical Benefits Entitlement File and entitlement cannot be established.

If the Medicare or Veteran file number provided in the pharmacists' claims is incorrect or the number and the name supplied do not match the Department of Human Services records to enable patient identification, an appropriate warning or rejection code will be returned to the pharmacy. These notifications of missing or incorrect Medicare or Veteran file numbers are provided to pharmacists in their reconciliation statement produced after the claim period has been paid by the Department of Human Services.

Special numbers are available for use in certain circumstances for eligible people who are unable to provide a Medicare number.

Concessional Patients

The Department of Human Services routinely validates a patient's entitlement to free or concessional benefits by checking concessional numbers in pharmacists' claims. If a number is not recorded correctly, a patient cannot be identified against the Department of Human Services' Pharmaceutical Benefits Entitlement File and entitlement cannot be established.

When a number is found to be from a card which was incorrect, expired at the time of supply or entitlement was withdrawn, warning or rejection codes will be returned to the pharmacy to assist with validation of concessional entitlement in relation to future claims from the same patient.

Entitlement checking procedures

General Patients

Once a pharmacist has been notified by the Department of Human Services of an incorrect Medicare or Veteran file number he/she should correct the number for future claims by:

- updating his/her system to reflect the correct number provided by the Department of Human Services (if patient consent to do so has been obtained); or
- speaking to the patient; or
- obtaining patient consent and calling the Department of Human Services on the Improved Monitoring of Entitlements (IME) (132 290 — select option 1).

If the patient presents a Medicare card that appears correct, but according to the Department of Human Services is not a valid number, or not a valid number for that person, a pharmacist may use a special number. A photocopy of the card, or a form must accompany the use of this number. The form is available on the Department of Human Services' website or by calling 132 290.

Concessional Patients

Once a pharmacist has been notified by the Department of Human Services of an incorrect concessional entitlement number, he/she should view the entitlement card to confirm the entitlement number, and start and end dates, when the patient next presents a PBS prescription.

Step by step

Pharmacists should take the following steps where concession entitlement does not appear to be valid or current:

- Re-confirm entitlement with the cardholder/customer;
- Contact the Department of Human Services on 132 290, with consent, to confirm the cardholder/customer concession status;
- If the Department of Human Services advises that the cardholder/customer is concessionally entitled to receive the PBS medicines on that day, supply the prescription as a concessional entitlement;
- If the Department of Human Services advises that the cardholder/customer is not concessionally entitled to receive the PBS medicines on that day, supply as a general prescription. Provide the customer with the information sheet "Your entitlement card" which explains entitlement checking to the customer and the steps they can follow if they are concessionally entitled.

7. How Pharmacists Claim Reimbursement: Information Required

The Department of Human Services uses a computerised system for pricing PBS prescriptions, repeat authorisations and prescriber bag supply orders, and for calculating claims.

The payment system is designed to pay pharmacists correctly for the pharmaceutical benefits they supply. It is essential instructions are followed carefully and that each document includes all relevant information. Accurate and complete data ensures claim payment is not delayed.

PBS Prescription identification

Pharmacists must include certain information on each PBS prescription sent in for claim, as specified below. It is important that this information is entered correctly and in the right place on the PBS prescription. This information will be included in a sticker produced by pharmacy software.

The sticker should be placed on the extreme left front of a PBS prescription, opposite each item being claimed. It must not obscure any details written by the prescriber. Most prescribers use PBS prescriptions, which have space for the sticker. If a sticker is not used, a PBS prescription identification stamp can be used or the information can be written in the same place, and in the same order.

Pharmacists should avoid writing over, or placing the sticker over, the prescriber number pre-printed on PBS/RPBS prescriptions, or the prescriber number box on PBS dental and optometrist, midwife and nurse practitioner prescriptions.

The sticker is not necessary for current repeat authorisation, prescriber bag supplies, or for old style authority PBS prescription and authority to prescribe forms, as they have printed spaces for the necessary details. However, it is required for the new format authority PBS prescription forms.

The following information should be entered next to the appropriate letter on the sticker or stamp:

- 'S' — the serial number for the claim
- 'A' —
 - the price claimed for pricing elected PBS prescriptions, exceptional PBS prescriptions and RPBS non-scheduled prescriptions (see under 'Extemporaneously-prepared pharmaceutical benefits not listed in the Standard Formulae List' for explanations of pricing elected PBS prescriptions and exceptional PBS prescriptions); and/or
 - confirmation that the PBS prescription is endorsed 'Regulation 24' or the RPBS prescription is endorsed 'hardship conditions apply'; and/or
 - a claim for a glass dropper bottle where applicable; and/or
 - any clarification of the prescription which will assist the Department of Human Services payment processing.
- 'No.' — the PBS prescription identifying number.

Serial numbers

PBS prescription, repeat authorisation, authority PBS prescription, and prescriber bag order forms submitted in each claim must bear consecutive serial numbers starting with:

- 1 – for prescriber bag supplies;
- 1 – for general benefits;
- C1 – for concessional and Safety Net Concession Card benefits;
- E1 – for Safety Net Entitlement Card benefits; and
- R1 – for RPBS benefits.

Each serial number should also be noted on any document kept by the pharmacist for record purposes.

Each prescriber bag item should be given a serial number, e.g., if there are five items on the first form in the claim, the first item on the second form in the claim will start with the serial number 6.

For prescriptions subject to the Safety Net 20 day rule, the serial number corresponds to the resulting payment category for the pharmaceutical benefit as supplied, not the patient's entitlement category.

Repeat authorisations for authority PBS prescriptions

When a benefit is supplied on a repeat authorisation which needed an authority PBS prescription, the serial number must be prefixed with the letter 'A' for a general benefit; 'AC' for a concessional benefit or a benefit supplied to a Safety Net Concession Card holder; 'AE' for a Safety Net Entitlement Card holder; or 'AR' for a RPBS benefit.

Repeat authorisations for deferred supply

When a benefit is supplied on a repeat authorisation prepared for deferred supply, the serial number must be prefixed with the letter 'D' for a general benefit; 'DC' for a concessional benefit or a benefit supplied to a Safety Net Concession Card holder; 'DE' for a Safety Net Entitlement Card holder; or 'DR' for a RPBS benefit.

Dropper containers

Dispensed prices for extemporaneously-prepared eye drops, ear drops and nasal instillations include the price of a polythene dropper container. However, if a glass dropper container is supplied, payment should be claimed by writing 'glass bottle' in box 'A' of the stamp.

Extemporaneously-prepared pharmaceutical benefits not listed in the Standard Formulae List

When a formula is not listed on the Standard Formulae List, the PBS prescription is paid at an average of 10 g/mL rate for the type of preparation, unless the pharmacist elects otherwise. A pharmacist may price an exceptional PBS prescription, or elect to price all non-pre-priced extemporaneous PBS prescriptions.

PBS prescriptions paid on an average price basis

If the PBS prescription is to be claimed as an exceptional PBS prescription, the pharmacist should write details of the formula supplied on the PBS prescription or repeat authorisation form; price the PBS prescription in accordance with the pricing principles (as detailed in '9. Pricing PBS Prescriptions'); and enter the calculated price on the sticker.

An exceptional PBS prescription is for an extemporaneously-prepared pharmaceutical benefit that is not included in the Standard Formulae List and for which the price of the ingredients (based on basic pricing rules) is twice or more than the recovery price of the ingredients calculated on an average price basis. Further information on pricing PBS prescriptions can be accessed from the book let titled *Explanation of Current Pricing* on the Department of Human Services' website at www.medicareaustralia.gov.au (PBS publications for Health Care Providers).

Pricing non-pre-priced extemporaneous preparations

Pharmacists should notify the Department of Human Services when they elect to price non-pre-priced extemporaneous preparations. Each PBS prescription should be priced in accordance with the pricing principles and that price entered on the sticker.

RPBS prescriptions for items not included in either the PBS or RPBS Schedule

When a prescription for a RPBS patient is for an item not included in either the PBS or the RPBS Schedule, the price claimed should be entered on the sticker. Full details on pricing and availability of such items under the RPBS are set out in the RPBS Explanatory Notes.

Payment to Pharmacists for Dispensing Premium-free Substitutable Medicines

Premium Free Dispensing Incentive payments will commence for eligible PBS listed products dispensed from 1 August 2008. Premium Free Dispensing Incentive payments will be available to approved suppliers to dispense a substitutable, premium-free medicine. The payment will be available only for PBS items which attract a Government subsidy. This includes PBS items supplied to DVA entitled consumers.

A number of conditions and criteria apply to receive this payment. Scripts will be assessed for validity and the Premium Free Dispensing Incentive payment will be paid by the Department of Human Services. Further information on this payment can be found on the Department of Human Services' website at:

www.medicareaustralia.gov.au/provider/pbs/pharmacists/reforms.jsp#dispensing

8. How Pharmacists Claim Reimbursement: Documents to be Submitted

A claim for pharmaceutical benefits consists of:

1. the original and duplicate of a completed Claim for Payment Form;
2. the original orders for prescriber bag supplies in a separate bundle;
3. the originals of all old format PBS prescriptions and authority PBS prescriptions, the Department of Human Services/DVA copies of new format PBS prescriptions and authority PBS prescriptions, and all repeat authorisations, separated into four bundles for benefits supplied to the general public; concessional beneficiaries/Safety Net Concession Card holders; Safety Net Entitlement Card holders and RPBS patients.

In order to satisfy auditing/spot check compliance measures, PBS prescriptions in each bundle should be in serial number order, with serial number 1 at the top of the bundle.

PBS prescriptions subject to the Safety Net 20 day rule are bundled according to the resulting payment category. For prescription forms with multiple PBS items, where the Safety Net 20 day rule would result in different payment categories for different items, dispensing via 'deferred supply' should be used where necessary to allow all items to be included in the correct bundles.

PBS prescriptions in the wrong bundle may be returned to the pharmacist for clarification. If appropriate, they can be resubmitted in the correct bundle in the next claim period.

Completing the claim form

The claimant's name, address of the pharmacy from which the pharmacist is approved to supply pharmaceutical benefits, approval number, and claim period number should be entered on the Claim for Payment Form. These details should match the latest written information held by the Department of Human Services, or payments can be delayed while clarification is sought.

The claim period number should state how many claims have been submitted so far in a calendar year, e.g., the sixth claim submitted by an approved pharmacist in 2005 should have a claim period number of 0506.

The first and last serial numbers given to items in each bundle are to be entered on the Claim for Payment Form.

A total claim amount is not required – this will be calculated by the Department of Human Services after the PBS prescriptions have been individually priced.

The declaration must be signed by the pharmacist approved to supply pharmaceutical benefits, unless he/she has made arrangements through the Department of Human Services for another pharmacist to sign it.

Lodging claims

A claim may be lodged at any time during the month at the relevant the Department of Human Services State office. Unless other arrangements have been made with the Department of Human Services, the following conditions apply:

- only one claim period can exist and only one claim can be lodged per month;
- the claim period shall cover pharmaceutical benefits supplied during one month; and
- the claim shall be sent within 30 days from when the benefits were supplied.

Claims for pharmaceutical benefits supplied over 18 months earlier may not be accepted for computer processing. Pharmacists with such claims should contact the Department of Human Services.

Reconciliation statements

As mentioned earlier, a pharmacist will receive a PBS reconciliation statement after a claim period has been processed. It provides details of each prescription for each brand of each pharmaceutical benefit item supplied in that claim period.

Reasons for non-payment of any item are coded, with the code numbers explained in the statement.

PBS prescriptions and repeat authorisations not accepted for payment will be returned, with the exception of PBS prescriptions with a dispensed price equal to or less than the patient contribution. Any other items on those PBS prescriptions that have been paid will have been cancelled.

If a PBS prescription was not accepted and can be re-submitted, it must be given a new serial number and included in a subsequent claim period.

If a PBS prescription is finally rejected for payment and a pharmacist is not satisfied with the decision, he/she may apply to the Administrative Appeals Tribunal for a review of that decision.

9. Pricing PBS Prescriptions

Pricing principles

The same pricing principles apply to all PBS prescriptions.

For ready-prepared pharmaceutical benefits, payment is made on the basis of the lowest-priced brand.

For a pharmaceutical benefit not listed as a ready-prepared item, and where a formulation title is stated but no formulary specified, payment is made on the basis of precedence given to formularies by State/Territory legislation.

Prices published in the Schedule do not include any component for goods and services tax (GST).

Further information on pricing PBS prescriptions can be accessed from the booklet titled *Explanation of Current Pricing* on the Department of Human Services' website at www.medicareaustralia.gov.au (PBS publications for Health Care Providers).

Pricing dates

Ready-prepared pharmaceutical benefits are priced on the first day of April, August and December for items supplied as from each of those days respectively.

Extemporaneously-prepared pharmaceutical benefits and containers are priced on the first day of May each year for items supplied as from the first day of August that year.

Pricing ready-prepared items

For maximum quantities

The price payable for a pharmaceutical benefit is shown in the Schedule against the item. The price is for the maximum quantity available.

The maximum quantity of some pharmaceutical benefits, such as eye drops and oral suspensions, has been determined as a single pack corresponding to the manufacturer's pack. These packs cannot be broken, so if a PBS prescription calls for less, the maximum quantity should be supplied and claimed from the Department of Human Services. Packs not to be broken are indicated by a double dagger (‡) in the Schedule.

For lesser quantities

For items where the standard pack is the same as the maximum quantity, and the pack can be broken, the price payable for a lesser quantity is established as follows:

- an amount equal to the dispensing fee, and if applicable the dangerous drug fee, is deducted from the benefit price as shown in the Schedule;
- to this new amount, a wastage percentage is applied, determined from the Wastage Factor Table;
- then the amount equal to the dispensing fee, dangerous drug fee (if applicable), and appropriate container fee, is added.

In no case shall the price for a broken quantity be more than the dispensed price of the Schedule's maximum quantity.

When a standard pack is not the same as the maximum quantity, the price of the pharmaceutical benefit concerned has an asterisk next to it and the standard pack rate is set out in Section 3 of the Schedule. The price payable for the quantity supplied is established by:

- applying the appropriate wastage table percentage to the standard pack rate;
- then adding an amount equivalent to the dispensing fee, the dangerous drug fee where applicable, and the appropriate container fee.

In no case shall the supply of a broken quantity, which is less than the item's maximum quantity, cost more than the dispensed price for the maximum quantity.

No container fee is payable when the quantity of pharmaceutical benefit supplied is more than the quantity contained in the standard pack.

Wastage table percentage

The following Wastage Factor Table is used to calculate the price payable for quantities supplied from the standard pack.

Wastage Factor Table

Column A -	5, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100
Column B -	10, 18, 26, 32, 38, 44, 50, 54, 58, 62, 66, 70, 74, 78, 82, 86, 90, 94, 98, 100

The appropriate wastage table percentage is as follows:

1. the percentage of the amount supplied from the amount in the standard pack is determined; and
2. where this percentage is the same as a percentage listed in Column A of the table, the percentage used is the figure shown in Column B; or
3. where the percentage is not the same as a percentage in Column A, then the nearest upward percentage in Column A applies, and the percentage used is the figure in Column B.

For example, 24 tablets are supplied from a standard pack of 100. Thus 24 per cent of the number contained in the standard pack is supplied. As this percentage does not appear in Column A, the next higher (i.e., 25 per cent) is used. Reading down from 25 per cent to Column B, the wastage table percentage is found to be 38 per cent.

Pricing extemporaneously-prepared items

General

The price payable for supplying the maximum quantity of standard formula preparations is shown in the Standard Formulae List.

The following principles apply in determining prices of all pre-priced extemporaneous formulae on the list.

They also apply when a pharmacist elects to price extemporaneous PBS prescriptions outside the list, including exceptional PBS prescriptions.

The amount payable is the sum of:

- the recovery price of each ingredient as shown in the Drug Tariff;
- the price of the appropriate container as shown in the price section; and
- a dispensing fee as shown in the price section.

Pricing of ingredients

When the quantity dispensed is not specified in the Drug Tariff, the recovery price is as follows:

1. determine the basic pricing unit relative to the quantity dispensed by referring to the following table:

Quantity	Basic Pricing Unit
Up to and including 700 mg	100 mg price rate
Over 700 mg and up to and including 1 g	price as if 1 g
Over 1 g and up to and including 7 g	1 g price rate
Over 7 g and up to and including 10 g	price as if 10 g
Over 10 g and up to and including 80 g	10 g price rate
Over 80 g and up to and including 90 g	price as if 80 g
Over 90 g	100 g price rate

2. find the recovery price of the basic pricing unit by applying the following quantity divisors to the recovery price shown for the ingredient in the Drug Tariff:
 - o 100 g price is 500 g price divided by 5, or 1 kg price divided by 10
 - o 10 g price is 100 g price plus 12.5 per cent divided by 10
 - o 1 g price is 10 g price plus 25 per cent divided by 10
 - o 100 mg price is 1 g price plus 25 per cent divided by 10
3. find the recovery price by multiplying the price of the basic pricing unit – as established in 2 – by the fraction that the quantity dispensed bears to the basic pricing unit.

For pricing purposes the quantity is to be taken to the next upward 50 milligrams or 0.05 millilitres.

The minimum recovery price for any ingredient is one cent. In other cases where a fraction of a cent occurs, the price is to be taken to the nearest cent (a half cent being taken up to the next cent).

In no case shall the recovery price for a quantity of an ingredient exceed the recovery price for a greater quantity of that ingredient.

Where liquids are purchased by weight, the recovery price includes the 'Specific Gravity Factor'.

Special pricing provisions apply to drugs marked '(a)' or '(b)' in the Drug Tariff.

For drugs marked '(a)', the pricing rules shown above apply to quantities up to the quantity listed in the Drug Tariff. Greater quantities are priced on a linear basis: the recovery price is ascertained by multiplying the fraction that the quantity dispensed bears to the quantity listed in the Drug Tariff by the price shown for the quantity listed.

Drugs marked '(b)' are packed sterile or are unstable, and all quantities are priced as if whole pack(s) were required. The recovery price is ascertained by multiplying the fraction that the quantity dispensed bears to the quantity listed in the Drug Tariff, taken to the next whole number, by the price shown for the quantity listed.

Pricing PBS prescriptions where extra ingredients are added to a formula

Where the vehicle is liquid and one or more solid ingredients are added, displacement of the liquid by the solid ingredients is disregarded for pricing purposes.

Containers

When a quantity is for more than the container sizes listed in this Schedule, payment will be made as if that quantity had been supplied in the minimum number of containers necessary to supply that quantity.

A double size container is allowed for bulk powders.

Special provisions for extemporaneous PBS prescriptions outside the Standard Formulae List

If a pharmacist elects to price extemporaneous PBS prescriptions outside the Standard Formulae List, there can be no variation for three months. This applies to all extemporaneously-prepared formulae not on the list, and includes both PBS and RPBS prescriptions.

If a pharmacist does not elect to price out these PBS prescriptions, he/she will be paid at an average reimbursement rate.

Under this system, payment is made on the basis of an average 10 g/mL rate applied to the category of preparation concerned, i.e., the price will be determined by multiplying the appropriate 10 g/mL rate by the number of 10 g/mL units supplied and adding container and dispensing fees. For example, an 80 mL mixture would be priced at eight times the average 10 mL rate for mixtures, with container and dispensing fee added.

The average 10 g/mL rate for each type of preparation is calculated monthly. It applies to PBS prescriptions supplied in the following month.

PBS prescriptions ordering a combination of standard formula preparations fall outside the scope of the Standard Formulae List and therefore are subject to this section.

Any variant to a formula included in the list (adding or deleting an ingredient or varying the dose) takes the formula dispensed outside the list.

When an ingredient is added to a standard formula and the recovery price for the standard formula plus additive under the average price system is less than for the standard formula alone, the pharmacist may have the PBS prescription priced as a basic standard formula item.

10. Miscellaneous

References

This Schedule identifies monographs of the British Pharmacopoeia, the British Pharmaceutical Codex, and the Australian Pharmaceutical Formulary and Handbook by the letters BP, BPC and APF respectively. References to all editions of the BPC and to earlier editions of the BP and APF also include the year of publication or the number of the edition.

Standards

Pharmacists can only supply under the PBS medicines which, or whose ingredients, conform to the standards of composition or purity prescribed. These standards are those specified in the *Therapeutic Goods Act 1989*.

Legislation

Copies of the *National Health Act 1953* and the *National Health (Pharmaceutical Benefits) Regulations 1960* are available from Government AusInfo shops in each capital city. The Act and the Regulations may also be accessed through the Attorney-General's Department website at www.comlaw.gov.au.

Nurse practitioner PBS prescribing

MEDICINES WHICH MAY BE PRESCRIBED BY AUTHORISED NURSE PRACTITIONERS

From 1 September 2010, nurse practitioners endorsed to prescribe under state or territory legislation can apply for approval as PBS prescribers (*authorised nurse practitioners*). Information for nurse practitioners to become authorised PBS prescribers is available from the Department of Human Services.

The medicines listed for prescribing by authorised nurse practitioners from 1 November 2010 are identified by 'NP' in the PBS Schedule. Nurse practitioners must not write PBS prescriptions for other medicines.

PBS prescribing is limited by a nurse practitioner's scope of practice, and state and territory prescribing rights. Prescribing of PBS medicines is also contingent on a prescriber being an *authorised nurse practitioner* and having collaborative arrangements in place, as required by amendments to the *National Health Act 1953*.

The Pharmaceutical Benefits Advisory Committee (PBAC) is responsible for making recommendations to the Minister for Health regarding medicines for prescribing by authorised nurse practitioners.

Further to prescribing within collaborative arrangements, certain medicines also have additional conditions for prescribing by nurse practitioners, as recommended by the PBAC. These medicines are identified by the codes 'CTO' for continuation therapy only or 'SCM' for prescribing within a shared care model, as outlined below:

- *Continuing therapy only model*

Where the patient's treatment and prescribing of a medicine has been initiated by a medical practitioner, but prescribing is continued by a nurse practitioner. (This is similar to existing arrangements between specialists and medical practitioners for prescribing certain medicines.)

- *Shared care model*

Where care is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed plan to manage the patient, in a patientcentred model of care. The details surrounding shared care arrangements will depend on the practitioners involved, patient needs and the healthcare context.

Some medicines are included in more than one section of the Schedule, and for more than one prescriber type. For a prescription to be eligible for subsidy, prescribers must ensure that they prescribe under the PBS only those medicines, and in accordance with the restrictions, listed for their prescriber type. Listing details for the same product may differ between sections and different PBS item codes apply for each prescriber type.

Nurse practitioner PBS prescriptions are identifiable by colour, and include the indicator 'NP' on personalised forms and a tick box on non-personalised (blank) forms.

Prescriptions must include the nurse practitioner's PBS prescriber number. For unrestricted and restricted PBS medicines, midwives/nurse practitioners can use the personalised or non-personalised PBS prescriber forms. For authority required and authority required (streamlined) PBS medicines, midwives/nurse practitioners can use the authority personalised or non-personalised PBS prescriber forms. Nurse practitioner PBS prescriptions may include repeats.

Regulation 24 applies for nurse practitioner prescribing. A nurse practitioner can direct that original and repeat supplies of pharmaceutical benefits be supplied at the one time, if certain conditions are satisfied.

Authority prescriptions: Authority prescriptions for authority required items, or for increased quantities or repeats, require prior approval from the Department of Human Services for each prescription. (Refer to Prescribing Medicines — Information for PBS prescribers and Supplying medicines — What Pharmacists Need to Know, for more information on authority prescriptions.)

State and territory requirements: Nurse practitioners may prescribe medicines as private prescriptions according to their state/territory prescribing accreditation. The medicines which can be prescribed differ between states and territories. It is the nurse practitioner's responsibility to ensure adherence to State/Territory law for all prescriptions (PBS and private) and additionally to all PBS requirements for PBS prescriptions.

Midwife PBS prescribing

MEDICINES WHICH MAY BE PRESCRIBED BY AUTHORISED MIDWIVES

From 1 September 2010, midwives endorsed to prescribe under state or territory legislation can apply for approval as PBS prescribers (*authorised midwives*). Information for midwives to become authorised PBS prescribers is available from the Department of Human Services.

The medicines listed for prescribing by authorised midwives are identified by 'MW' in the PBS Schedule. Midwives must not write PBS prescriptions for other medicines.

PBS prescribing by midwives is limited by state and territory prescribing rights. It is also contingent on a prescriber being an *authorised midwife* and having collaborative arrangements in place, as required by amendments to the *National Health Act 1953*.

The Pharmaceutical Benefits Advisory Committee (PBAC) is responsible for making recommendations to the Minister for Health regarding medicines for prescribing by authorised midwives.

Some medicines are included in more than one section of the Schedule, and for more than one prescriber type. For a prescription to be eligible for subsidy, prescribers must ensure that they prescribe under the PBS only those medicines, and in accordance with the restrictions, listed for their prescriber type. Listing details for the same product may differ between sections and different PBS item codes apply for each prescriber type.

Midwife PBS prescriptions are identifiable by colour, and include the indicator 'MW' on personalised forms and a tick box on non-personalised (blank) forms. Prescriptions must include the midwife's PBS prescriber number. For unrestricted and restricted PBS medicines, midwives/nurse practitioners can use the personalised or non-personalised PBS prescriber forms. For authority required and authority required (streamlined) PBS medicines, midwives/nurse practitioners can use the authority personalised or non-personalised PBS prescriber forms. Midwife PBS prescriptions may include repeats.

Regulation 24 applies for midwife prescribing. A midwife can direct that original and repeat supplies of pharmaceutical benefits be supplied at the one time, if certain conditions are satisfied.

Authority prescriptions: Authority prescriptions for authority required items, or for increased quantities or repeats, require prior approval from the Department of Human Services for each prescription. (Refer to Prescribing Medicines—Information for PBS prescribers and Supplying Medicines — What Pharmacists Need to Know, for more information on authority prescriptions.)

State and Territory requirements: Midwives may prescribe medicines as private prescriptions according to their state/territory prescribing accreditation. The medicines which can be prescribed differ between states and territories. It is the midwife's responsibility to ensure adherence to state/territory law for all prescriptions (PBS and private) and additionally to all PBS requirements for PBS prescriptions.

Optometrist PBS prescribing

PREPARATIONS WHICH MAY BE PRESCRIBED BY AUTHORISED OPTOMETRISTS

From 1 January 2008, optometrists accredited to prescribe under State or Territory legislation can apply for approval as PBS prescribers (*authorised optometrists*). Information for optometrists on becoming a PBS prescriber is available from the Department of Human Services.

The medications listed for prescribing by authorised optometrists are identified by 'OP' in the PBS Schedule. Optometrists must not write PBS prescriptions for any other medicines listed on the PBS.

The Pharmaceutical Benefits Advisory Committee (PBAC) is responsible for making recommendations to the Minister of Health regarding preparations for prescribing by authorised optometrists.

Some products are included in more than one section of the Schedule, and for more than one prescriber type. For a prescription to be eligible for subsidy, prescribers must ensure that they prescribe under the PBS only those medicines, and in accordance with the restrictions, listed for their practitioner type.

Optometrist PBS prescriptions are identifiable by colour, and include the words 'PBS/RPBS optometrist'. Prescriptions must include the optometrist's PBS prescriber number. The same optometrist prescription form is used to prescribe unrestricted, restricted or authority items. Only one item is allowed per form. Optometrist PBS prescriptions may include repeats.

Regulation 24 does not apply for optometrist prescribing. An optometrist cannot direct that original and repeat supplies of pharmaceutical benefits be supplied at the one time.

Authority prescriptions: Authority prescriptions for authority required items, or for increased quantities or repeats, require prior approval from the Department of Human Services or the Department of Veterans' Affairs (DVA) for each prescription. (Refer to Prescribing Medicines — Information for PBS prescribers and Supplying Medicines — What Pharmacists Need to Know, for more information on authority prescriptions.) DVA approval for non-Schedule items is not available for optometrist prescribing.

RPBS: Optometrists approved as PBS prescribers may write prescriptions for supply under the RPBS. The medicines available for prescribing by authorised optometrists under the RPBS are the same as those available under the PBS. There are no optometrist listings in the Repatriation Schedule for prescribing for veterans only. There is no provision for optometrist prescribers to request approval to prescribe items that are not included in the PBS Schedule (non-Schedule items).

State and Territory requirements: Optometrists may prescribe medications as private prescriptions according to their State/Territory prescribing accreditation. The medicines which can be prescribed differ between States and Territories. It is the optometrist's responsibility to ensure adherence to State/Territory law for all prescriptions (PBS and private) and additionally to all PBS requirements for PBS/RPBS prescriptions.

GUIDELINES FOR SHARED CARE OF GLAUCOMA PATIENTS

Under these guidelines, authorised optometrists who are approved to use therapeutic drugs in their practices and who have adequate professional indemnity cover, will be able to co-manage glaucoma patients in a shared care arrangement with an ophthalmologist.

By writing a PBS prescription for the treatment of glaucoma, the prescriber is certifying the criteria set out in these guidelines are satisfied, and use of the drug is in accordance with the registered indications – refer to the current Product Information for details.

Note that all anti-glaucoma drugs listed on the PBS for prescribing by authorised optometrists must be delivered in a shared care model.

Initial Referral to Ophthalmologist

An authorised optometrist who makes a provisional diagnosis of glaucoma is to refer the patient to an ophthalmologist for confirmation of the diagnosis and the development of a management plan.

Where clinically important delays are expected before the patient's first review by an ophthalmologist, the optometrist should seek interim advice on the patient's management from the ophthalmologist by telephone (or alternate means).

The patient's consent is to be obtained by the ophthalmologist and optometrist for all aspects of the management plan, including the sharing of care between the two practitioners, and the communication of clinical information to the patient's nominated general practitioner.

Patients being considered for anti-glaucoma therapy with a beta blocking agent should be assessed for any potential cardiovascular or respiratory risk by a medical practitioner (often the patient's general practitioner), prior to initiating therapy. This assessment should be repeated if a change in dose of the beta blocker is proposed.

Once the diagnosis of glaucoma is confirmed by the ophthalmologist and a treatment plan is in place for the patient, the optometrist can perform ongoing reviews to monitor the patient and prescribe topical drugs under the PBS providing that:

- Periodic review demonstrates the treatment to be effective, and
- Changes to management are only initiated following consultation between treating practitioners.

Patient Management Plan

The management plan must be in writing and specify the following:

1. All the agreed components of treatment including any drug therapy;
2. Target pressures and action to be taken if these are not achieved within a specified time frame;
3. An agreed approach to monitoring visual fields and optic disc imaging and action to be taken following changes in visual fields;
4. Triggers for referral for more immediate ophthalmological and general practitioner review;
5. Likely side effects from agreed treatment and the action to be taken to address these;
6. An agreed schedule for patient review by both practitioners;
7. Who is responsible for performing each of the required tests and the required frequency for performing them;
8. An agreed method for timely communication of clinical findings and patient management between the two practitioners and the patient's nominated general practitioner.

Ophthalmologists must be available for consultation by the treating optometrist and for consultation by the patient where that consultation has been recommended or requested by the optometrist.

The involvement of a pharmacist to provide medicines information, advice relating to administration and techniques to limit systemic absorption and side effects of ophthalmic medications is recommended.

Therapeutic Index

ALIMENTARY TRACT AND METABOLISM	60
STOMATOLOGICAL PREPARATIONS.....	60
STOMATOLOGICAL PREPARATIONS.....	60
DRUGS FOR ACID RELATED DISORDERS.....	60
ANTACIDS.....	60
DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)	60
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	67
BELLADONNA AND DERIVATIVES, PLAIN	67
PROPULSIVES	67
ANTIEMETICS AND ANTINAUSEANTS	68
ANTIEMETICS AND ANTINAUSEANTS.....	68
BILE AND LIVER THERAPY	72
BILE THERAPY.....	72
DRUGS FOR CONSTIPATION.....	73
DRUGS FOR CONSTIPATION.....	73
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	76
INTESTINAL ANTIINFECTIVES	76
ELECTROLYTES WITH CARBOHYDRATES	77
ANTIPROPULSIVES	77
INTESTINAL ANTIINFLAMMATORY AGENTS.....	77
DIGESTIVES, INCL. ENZYMES.....	80
DIGESTIVES, INCL. ENZYMES.....	80
DRUGS USED IN DIABETES.....	81
INSULINS AND ANALOGUES.....	81
BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS.....	83
VITAMINS.....	100
VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO	100
VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12	100
MINERAL SUPPLEMENTS	101
CALCIUM	101
POTASSIUM	101
OTHER MINERAL SUPPLEMENTS	101
ANABOLIC AGENTS FOR SYSTEMIC USE.....	101
ANABOLIC STEROIDS.....	101
OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS.....	102
OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS	102
BLOOD AND BLOOD FORMING ORGANS	104
ANTITHROMBOTIC AGENTS.....	104
ANTITHROMBOTIC AGENTS.....	104
ANTIHEMORRHAGICS	118
ANTIFIBRINOLYTICS	118
ANTIANEMIC PREPARATIONS	118
IRON PREPARATIONS.....	118
VITAMIN B12 AND FOLIC ACID.....	119
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS.....	119
BLOOD AND RELATED PRODUCTS.....	119
I.V. SOLUTIONS	119
OTHER HEMATOLOGICAL AGENTS.....	120
OTHER HEMATOLOGICAL AGENTS.....	120
CARDIOVASCULAR SYSTEM.....	121
CARDIAC THERAPY	121
CARDIAC GLYCOSIDES.....	121
ANTIARRHYTHMICS, CLASS I AND III	121
CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES	122
VASODILATORS USED IN CARDIAC DISEASES	123
OTHER CARDIAC PREPARATIONS	124
ANTIHYPERTENSIVES	125
ANTIADRENERGIC AGENTS, CENTRALLY ACTING	125

ANTIADRENERGIC AGENTS, PERIPHERALLY ACTING	125
ARTERIOLEAR SMOOTH MUSCLE, AGENTS ACTING ON.....	125
DIURETICS	126
LOW-CEILING DIURETICS, THIAZIDES	126
LOW-CEILING DIURETICS, EXCL. THIAZIDES	126
HIGH-CEILING DIURETICS.....	126
POTASSIUM-SPARING AGENTS	127
DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION	127
PERIPHERAL VASODILATORS	128
PERIPHERAL VASODILATORS.....	128
BETA BLOCKING AGENTS	128
BETA BLOCKING AGENTS	128
CALCIUM CHANNEL BLOCKERS	132
SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS	132
SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS	133
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM.....	134
ACE INHIBITORS, PLAIN.....	134
ACE INHIBITORS, COMBINATIONS	140
ANGIOTENSIN II ANTAGONISTS, PLAIN.....	143
ANGIOTENSIN II ANTAGONISTS, COMBINATIONS	147
LIPID MODIFYING AGENTS.....	156
LIPID MODIFYING AGENTS, PLAIN	156
LIPID MODIFYING AGENTS, COMBINATIONS	172
DERMATOLOGICALS	192
ANTIFUNGALS FOR DERMATOLOGICAL USE.....	192
ANTIFUNGALS FOR TOPICAL USE	192
ANTIFUNGALS FOR SYSTEMIC USE.....	192
ANTIPSORIATICS	193
ANTIPSORIATICS FOR TOPICAL USE	193
ANTIPSORIATICS FOR SYSTEMIC USE	194
ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE.....	194
CHEMOTHERAPEUTICS FOR TOPICAL USE	194
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS.....	195
CORTICOSTEROIDS, PLAIN	195
ANTI-ACNE PREPARATIONS	197
ANTI-ACNE PREPARATIONS FOR TOPICAL USE	197
ANTI-ACNE PREPARATIONS FOR SYSTEMIC USE	197
OTHER DERMATOLOGICAL PREPARATIONS.....	198
OTHER DERMATOLOGICAL PREPARATIONS.....	198
GENITO URINARY SYSTEM AND SEX HORMONES.....	200
OTHER GYNECOLOGICALS.....	200
OXYTOCICS.....	200
CONTRACEPTIVES FOR TOPICAL USE	200
OTHER GYNECOLOGICALS.....	200
SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM	201
HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	201
ANDROGENS	202
ESTROGENS.....	206
PROGESTOGENS.....	207
PROGESTOGENS AND ESTROGENS IN COMBINATION	208
GONADOTROPINS AND OTHER OVULATION STIMULANTS.....	209
ANTIANDROGENS	210
OTHER SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM	211
UROLOGICALS.....	212
UROLOGICALS	212
DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY.....	213
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS.....	214
PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES	214
ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES	214
POSTERIOR PITUITARY LOBE HORMONES	214
HYPOTHALAMIC HORMONES	215
CORTICOSTEROIDS FOR SYSTEMIC USE	215

CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN	215
THYROID THERAPY	219
THYROID PREPARATIONS	219
ANTITHYROID PREPARATIONS	219
PANCREATIC HORMONES	220
GLYCOGENOLYTIC HORMONES	220
CALCIUM HOMEOSTASIS	220
PARATHYROID HORMONES AND ANALOGUES	220
ANTI-PARATHYROID AGENTS	221
ANTIINFECTIVES FOR SYSTEMIC USE	223
ANTIBACTERIALS FOR SYSTEMIC USE	223
TETRACYCLINES	223
BETA-LACTAM ANTIBACTERIALS, PENICILLINS	224
OTHER BETA-LACTAM ANTIBACTERIALS	231
SULFONAMIDES AND TRIMETHOPRIM	237
MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS	237
AMINOGLYCOSIDE ANTIBACTERIALS	240
QUINOLONE ANTIBACTERIALS	242
OTHER ANTIBACTERIALS	243
ANTIMYCOTICS FOR SYSTEMIC USE	245
ANTIMYCOTICS FOR SYSTEMIC USE	245
ANTIMYCOBACTERIALS	249
DRUGS FOR TREATMENT OF TUBERCULOSIS	249
DRUGS FOR TREATMENT OF LEPRA	249
ANTIVIRALS FOR SYSTEMIC USE	250
DIRECT ACTING ANTIVIRALS	250
VACCINES	255
BACTERIAL VACCINES	255
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	256
ANTINEOPLASTIC AGENTS	256
ALKYLATING AGENTS	256
ANTIMETABOLITES	258
PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS	259
CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES	259
OTHER ANTINEOPLASTIC AGENTS	259
ENDOCRINE THERAPY	291
HORMONES AND RELATED AGENTS	291
HORMONE ANTAGONISTS AND RELATED AGENTS	294
IMMUNOSTIMULANTS	299
IMMUNOSTIMULANTS	299
IMMUNOSUPPRESSANTS	304
IMMUNOSUPPRESSANTS	304
MUSCULO-SKELETAL SYSTEM	490
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	490
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS	490
SPECIFIC ANTIRHEUMATIC AGENTS	495
MUSCLE RELAXANTS	496
MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS	496
MUSCLE RELAXANTS, DIRECTLY ACTING AGENTS	496
ANTIGOUT PREPARATIONS	497
ANTIGOUT PREPARATIONS	497
DRUGS FOR TREATMENT OF BONE DISEASES	497
DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION	497
NERVOUS SYSTEM	511
ANALGESICS	511
OPIOIDS	511
OTHER ANALGESICS AND ANTIPYRETICS	523
ANTIMIGRAINE PREPARATIONS	524
ANTIEPILEPTICS	527
ANTIEPILEPTICS	527
ANTI-PARKINSON DRUGS	538
ANTICHOLINERGIC AGENTS	538

DOPAMINERGIC AGENTS	539
PSYCHOLEPTICS	543
ANTIPSYCHOTICS	543
ANXIOLYTICS	560
HYPNOTICS AND SEDATIVES	561
PSYCHOANALEPTICS	563
ANTIDEPRESSANTS	563
PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS	573
ANTI-DEMENTIA DRUGS	576
OTHER NERVOUS SYSTEM DRUGS	584
PARASYMPATHOMIMETICS	584
DRUGS USED IN ADDICTIVE DISORDERS	584
OTHER NERVOUS SYSTEM DRUGS	588
ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS.....	591
ANTIPROTOZOALS	591
AGENTS AGAINST AMOEBIASIS AND OTHER PROTOZOAL DISEASES.....	591
ANTIMALARIALS.....	591
ANTHELMINTICS	592
ANTITREMATODALS.....	592
ANTINEMATODAL AGENTS	592
ECTOPARASITICIDES, INCL. SCABICIDES, INSECTICIDES AND REPELLENTS.....	593
ECTOPARASITICIDES, INCL. SCABICIDES	593
RESPIRATORY SYSTEM.....	594
NASAL PREPARATIONS.....	594
DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE	594
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES.....	594
ADRENERGICS, INHALANTS.....	594
OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS	600
ADRENERGICS FOR SYSTEMIC USE.....	602
OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	603
COUGH AND COLD PREPARATIONS	604
COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS.....	604
ANTIHISTAMINES FOR SYSTEMIC USE	604
ANTIHISTAMINES FOR SYSTEMIC USE.....	604
SENSORY ORGANS.....	605
OPHTHALMOLOGICALS.....	605
ANTIINFECTIVES.....	605
ANTIINFLAMMATORY AGENTS	607
ANTIGLAUCOMA PREPARATIONS AND MIOTICS	608
MYDRIATICS AND CYCLOPLEGICS	614
DECONGESTANTS AND ANTIALLERGICS.....	614
OCULAR VASCULAR DISORDER AGENTS	614
OTHER OPHTHALMOLOGICALS	618
OTOLOGICALS	624
ANTIINFECTIVES.....	624
CORTICOSTEROIDS AND ANTIINFECTIVES IN COMBINATION	624
OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS.....	625
ANTIINFECTIVES.....	625
VARIOUS.....	626
ALLERGENS	626
ALLERGENS	626
ALL OTHER THERAPEUTIC PRODUCTS.....	626
ALL OTHER THERAPEUTIC PRODUCTS.....	626
DIAGNOSTIC AGENTS.....	629
URINE TESTS	629
OTHER DIAGNOSTIC AGENTS.....	629
GENERAL NUTRIENTS.....	632
OTHER NUTRIENTS.....	632
Pharmaceutical Benefits for Palliative Care.....	661
ALIMENTARY TRACT AND METABOLISM	662

STOMATOLOGICAL PREPARATIONS.....	662
STOMATOLOGICAL PREPARATIONS.....	662
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS.....	662
BELLADONNA AND DERIVATIVES, PLAIN	662
DRUGS FOR CONSTIPATION.....	662
DRUGS FOR CONSTIPATION.....	662
MUSCULO-SKELETAL SYSTEM.....	667
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	667
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS.....	667
NERVOUS SYSTEM	671
ANALGESICS.....	671
OPIOIDS	671
OTHER ANALGESICS AND ANTIPYRETICS	673
ANTIEPILEPTICS.....	674
ANTIEPILEPTICS.....	674
PSYCHOLEPTICS	674
ANXIOLYTICS.....	674
HYPNOTICS AND SEDATIVES	675

Section 2 – READY-PREPARED PHARMACEUTICAL BENEFITS

SYMBOLS USED IN THE SCHEDULE

An asterisk (*) against the dispensed price of a benefit indicates that the manufacturer's pack does not coincide with the maximum quantity.

A double dagger (‡) in the maximum quantity column indicates an item for which the maximum quantity has been specially determined to correspond to the manufacturer's pack and the manufacturer's standard pack should be prescribed and supplied. For any item where a maximum quantity greater than 1 is marked with a double dagger (‡), that maximum quantity should be prescribed and supplied.

A gauge sign (#) against the dispensed price of a benefit indicates that the product is not preconstituted and that an extemporaneously-prepared dispensing fee is included in the dispensed price and, where appropriate, an amount for purified water.

Where a STATE is indicated after a manufacturer's code, that brand may be available only in the State indicated. NSW–(N); Vic–(V); Qld–(Q); SA–(S); WA–(W); Tas–(T).

RESTRICTED BENEFITS

All restricted items have separate headings for authority and non-authority items. In each case these items may be prescribed as pharmaceutical benefits only for use for one of the specified indications. Where more than one indication is specified for an Authority required or Restricted pharmaceutical benefit, each indication is separated from the preceding indication by a semi-colon and commences on the next line. In the case of Authority required (STREAMLINED) items, each indication will also include a four digit streamlined authority code. The drug may be prescribed as a pharmaceutical benefit for a patient who qualifies under any of the specified indications.

A straight line is drawn between entries for different forms and strengths of an item to indicate clearly the different restrictions which apply to these various forms and strengths.

The maximum quantity and/or number of repeats in respect of an item shown in the Schedule may be varied by the Chief Executive Medicare when approving an Authority Prescription or an Authority to Prescribe. The quantity and number of repeats shown on the authority shall be supplied. (See Explanatory Notes). Payment will be made on the basis of the price shown for that item in the Schedule.

BRAND EQUIVALENCE

'a' located immediately before brand names of a particular strength of an item indicates that the sponsors of these brands have submitted evidence that they have been demonstrated to be bioequivalent or therapeutically equivalent, or that justification for not needing bioequivalence or therapeutic equivalence data has been provided to and accepted by the Therapeutic Goods Administration. It would thus be expected that these brands may be interchanged without differences in clinical effect.

For other brands of an item, i.e., those not indicated as above, it is unknown whether or not they are equivalent. There may be several reasons for this, such as bioequivalence data not being considered necessary when the products were approved for marketing, or that advice or data have not been forthcoming from sponsors. This does not necessarily suggest a lack of safety or efficacy, but in these circumstances caution should be taken if brands are interchanged.

'b' attached to brand names indicates that these brands are also equivalent, but that it is not known if there is equivalence between brands marked 'a' and brands marked 'b'.

BRAND PREMIUM POLICY

The Brand Premium Policy was introduced on 1 December 1990 to increase price competition by allowing pharmaceutical manufacturers to set their own price on multi-branded items listed on the Pharmaceutical Benefits Scheme and to encourage the development of the generic pharmaceutical industry in Australia. The policy does this by increasing prescribers' and patients' consciousness about the price of drugs. In effect, it makes both groups question whether it is necessary for the patient to pay more for the drugs when a cheaper brand is available. The policy also allows companies to establish prices taking into account competition and consumer acceptance.

The policy operates where there is more than one brand of a particular drug available through the Pharmaceutical Benefits Scheme and where the brands are therapeutically interchangeable. Due to this, the policy mainly applies to out of patent drugs.

Basically the policy operates by:

- the Australian Government subsidising a drug to the level of the lowest priced brand (except in those instances where the lowest priced brand has, as part of its price, a therapeutic group premium);
- suppliers of other brands of that drug being able to set a price above the price charged by the supplier(s) of the lowest priced brand(s); and
- the patient paying the brand premium which is the price difference between the lowest price brand and the brand prescribed.

If a prescription is written generically or for the lowest priced brand, and the lowest priced brand is supplied, there is no brand premium payable.

'B' located immediately before an amount in the premium column indicates a brand premium which applies to that particular brand of the item.

If a brand of a drug which is subject to a therapeutic group premium also has a brand premium, there will be two amounts shown on separate lines in the premium column, prefixed by 'T' and 'B' respectively.

If a brand of a drug which is subject to a special patient contribution also has a brand premium, there will be two amounts shown on separate lines in the premium column, prefixed by 'S' and 'B' respectively.

THERAPEUTIC GROUP PREMIUM POLICY

The Therapeutic Group Premium Policy was introduced on 1 February 1998 as an extension of the Brand Premium Policy to encourage greater competition between manufacturers of drugs and to make doctors and patients more aware of the costs of medicines.

The Therapeutic Group Premium policy applies within narrowly defined therapeutic sub-groups where the drugs concerned are of similar safety, efficacy and health outcomes.

Basically the policy operates by:

- the Australian Government subsidising drugs within a defined therapeutic sub-group to the level of the lowest priced drug in the sub-group;
- suppliers of other drugs within that sub-group being able to set prices above the price charged by the supplier(s) of the lowest priced drug; and
- the patient paying the therapeutic group premium which is the price difference between the lowest price drug and the drug prescribed.

'T' located immediately before an amount in the premium column indicates a therapeutic group premium which applies to that particular item.

If a brand of a drug which is subject to a therapeutic group premium also has a brand premium, there will be two amounts shown on separate lines in the premium column, prefixed by 'T' and 'B' respectively.

The success of the Government in controlling prices of products supplied through the Pharmaceutical Benefits Scheme has often been criticised by the pharmaceutical industry. Under both the Brand Premium Policy and the Therapeutic Group Premium Policy, suppliers of multi-branded items and therapeutically similar drugs are able to set their own prices at a level that they think the market will bear. At the same time, the prescriber and the patient can decide whether it is necessary to pay more for a particular brand or drug when a cheaper one is available and is therapeutically interchangeable.

The brand premium or therapeutic group premium does not count toward the patient's safety net.

It should be noted that the brand premium or therapeutic group premium is not a Government charge or revenue. The premium arises from the manufacturer's price and the majority goes to the manufacturer with wholesalers and pharmacists receiving a small percentage.

Prescriber Bag

PRESCRIBER BAG

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer	
3451P NP	ADRENALINE adrenaline 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules	1	20.68	Link Medical Products Pty Ltd	LM
3453R NP	ATROPINE ATROPINE Injection 600 micrograms in 1 mL, 10	1	20.88	Pfizer Australia Pty Ltd	PF
3457Y NP	BENZTROPINE benztropine mesylate 2 mg/2 mL injection, 5 x 2 mL ampoules	1	103.93	Cogentin	FK
3486L NP	BENZYLPENICILLIN benzylpenicillin 600 mg injection, 1 x 600 mg vial	5	*31.96	BenPen	CS
or	or				
3485K NP	PROCAINE PENICILLIN procaine penicillin 1.5 g/3.4 mL injection, 5 x 3.4 mL syringes	1	92.56	Cilicaine	QA
3487M NP	BENZYLPENICILLIN benzylpenicillin 3 g injection, 1 x 3 g vial	1	15.44	BenPen	CS
3478C NP	CLONAZEPAM clonazepam 2.5 mg/mL oral liquid, 10 mL	±1	11.07	Rivotril	RO
3472R NP	DEXAMETHASONE SODIUM PHOSPHATE DEXAMETHASONE SODIUM PHOSPHATE Injection equivalent to 4 mg dexamethasone phosphate in 1 mL, 5	1	17.96	^a Hospira Pty Limited	HH
				^a Dexmethsone	AF
or	or				
3470P NP	HYDROCORTISONE SODIUM SUCCINATE hydrocortisone (as sodium succinate) 100 mg injection [1 x 100 mg vial] (& inert substance diluent [1 x 2 mL vial], 1 pack	2	*18.04	Solu-Cortef	PF
or	or				
3471Q NP	HYDROCORTISONE SODIUM SUCCINATE hydrocortisone (as sodium succinate) 250 mg injection [1 x 250 mg vial] (& inert substance diluent [1 x 2 mL vial], 1 pack	1	16.83	Solu-Cortef	PF
3458B NP	DIAZEPAM diazepam 10 mg/2 mL injection, 5 x 2 mL ampoules	1	13.68	Hospira Pty Limited	HH
10244E NP	DIPHTHERIA TOXOID + TETANUS TOXOID diphtheria toxoid 2 Lf/0.5 mL + tetanus toxoid 2 Lf/0.5 mL injection, 10 x 0.5 mL vials	1	144.59	MassBiologics tetanus and diphtheria toxoids adsorbed	CS
or	or				
3463G NP	DIPHTHERIA TOXOID + TETANUS TOXOID diphtheria toxoid 2 international units/0.5 mL + tetanus toxoid 20 international units/0.5 mL injection, 5 x 0.5 mL syringes	2	*144.60	ADT Booster	CS
3466K NP	FRUSEMIDE frusemide 20 mg/2 mL injection, 5 x 2 mL ampoules	1	8.63	^a Lasix	SW
				^a Frusemide Sandoz	SZ
				^a Frusemide-Claris	AE
3467L NP	GLUCAGON HYDROCHLORIDE glucagon hydrochloride 1 mg injection [1 x 1 mg vial] (&) inert substance diluent [1 x 1 mL syringe], 1 pack	1	50.55	GlucaGen Hypokit	NO
3475X NP	GLYCERYL TRINITRATE glyceryl trinitrate 400 microgram/actuation spray, 200 actuations	±1	20.47	Nitrolingual Pumpspray	SW
3456X NP	HALOPERIDOL haloperidol 5 mg/mL injection, 10 x 1 mL ampoules	1	22.62	Serenace	QA
or	or				
3455W NP	CHLORPROMAZINE chlorpromazine hydrochloride 50 mg/2 mL injection, 10 x 2 mL ampoules	1	20.82	Largactil	SW

PRESCRIBER BAG

		Max. Qty (Packs)	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer	
Code	Name, Restriction, Manner of Administration and Form				
3473T NP	HYOSCINE BUTYLBROMIDE hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules	1	24.55	Buscopan	BY
10209H NP	LIGNOCAINE lignocaine hydrochloride anhydrous 1% (50 mg/5 mL) injection, 5 x 5 mL ampoules	1	37.67	Pfizer Australia Pty Ltd	PF
3489P	METHOXYFLURANE methoxyflurane 999.9 mg/g inhalation: solution, 1 x 3 mL bottle	1	45.12	Pentrox	DV
3476Y NP	METOCLOPRAMIDE metoclopramide hydrochloride 10 mg/2 mL injection, 10 x 2 mL ampoules	1	13.33	Maxolon	IA
or	or				
3477B NP	PROCHLORPERAZINE prochlorperazine mesylate 12.5 mg/mL injection, 10 x 1 mL ampoules	1	17.89	Stemetil	SW
10178Q NP	MIDAZOLAM midazolam 5 mg/mL injection, 10 x 1 mL ampoules	1	38.91	Pfizer Australia Pty Ltd	PF
3479D NP	MORPHINE morphine sulfate 15 mg/mL injection, 5 x 1 mL ampoules	1	17.30	Hospira Pty Limited	HH
or	or				
3480E NP	MORPHINE morphine sulfate 30 mg/mL injection, 5 x 1 mL ampoules	1	19.43	Hospira Pty Limited	HH
2200T NP	NALOXONE naloxone hydrochloride 400 microgram/mL injection, 1 x 1 mL syringe	10	*203.56	Naloxone minijet	UC
10251M	OXYTOCIN oxytocin 10 international units/mL injection, 5 x 1 mL ampoules	1	61.76	Oxytocin Sandoz	SZ
10213M	PHYTOMENADIONE phytomenadione 10 mg/mL injection, 5 x 1 mL ampoules	1	22.27	Konakion MM	RO
3488N NP	PROMETHAZINE promethazine hydrochloride 50 mg/2 mL injection, 5 x 2 mL ampoules	2	*30.58	Hospira Pty Limited	HH
3495Y NP	SALBUTAMOL salbutamol 100 microgram/actuation inhalation: pressurised, 200	‡1	11.62	^a Ventolin CFC-free	GK
3495Y NP	SALBUTAMOL salbutamol 100 microgram/actuation inhalation: pressurised, 200	‡1	10.45	^a Asmol CFC-free	AL
				^a APO-Salbutamol Inhaler	TX
or	or				
3496B NP	SALBUTAMOL salbutamol 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules	‡1	11.36	^a Butamol 2.5	QA
				^a Salbutamol-GA	GN
				^a APO-Salbutamol	TX
				^a Asmol 2.5 uni-dose	AF
				^a Salbutamol Sandoz	SZ
				^a GenRx Salbutamol	GX
				^a Pharmacor Salbutamol 2.5	CR
				^a Salbutamol Actavis	UA
3496B NP	SALBUTAMOL salbutamol 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules	‡1	11.96	^a Ventolin Nebules	GK
3497C NP	SALBUTAMOL salbutamol 5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules	‡1	11.60	^a Asmol 5 uni-dose	AF
				^a Butamol 5	QA

PRESCRIBER BAG

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	Dispensed Price for Max.		Brand Name and Manufacturer	
			Qty	\$		
					a APO-Salbutamol	TX
					a Salbutamol Actavis	UA
					a GenRx Salbutamol	GX
					a Pharmacor Salbutamol 5	CR
					a Salbutamol Sandoz	SZ
					a Salbutamol-GA	GN
3497C NP	SALBUTAMOL salbutamol 5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules	‡1	12.18		a Ventolin Nebules	GK
3484J NP	TRAMADOL tramadol hydrochloride 100 mg/2 mL injection, 5 x 2 mL ampoules	1	11.92		a Tramal 100	CS
					a Tramadol ACT	GN
					a Tramadol Sandoz	SZ

General Pharmaceutical Benefits

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	

ALIMENTARY TRACT AND METABOLISM

STOMATOLOGICAL PREPARATIONS

STOMATOLOGICAL PREPARATIONS

Antiinfectives and antiseptics for local oral treatment

AMPHOTERICIN B

2931G NP	amphotericin B 10 mg lozenge, 20	1	1	..	12.37	13.52	Fungilin	QA
3306B DP	amphotericin B 10 mg lozenge, 20	1	..	..	12.37	13.52	Fungilin	QA

NYSTATIN

3033P NP	nystatin 100 000 international units/mL oral liquid, 24 mL	±1	1	..	11.48	12.63	^a Mycostatin	FM
				^b 3.01	14.49	12.63	^a Nilstat	QA
3343Y DP	nystatin 100 000 international units/mL oral liquid, 24 mL	±1	..	..	11.48	12.63	^a Mycostatin	FM
				^b 3.01	14.49	12.63	^a Nilstat	QA

Other agents for local oral treatment

BENZYDAMINE

Restricted benefit

Radiation induced mucositis

1121B NP	benzylamine hydrochloride 0.15% mouthwash, 500 mL	±1	1	..	22.60	23.75	Diffiam	IA
5032W DP	benzylamine hydrochloride 0.15% mouthwash, 500 mL	±1	..	..	22.60	23.75	Diffiam	IA

DRUGS FOR ACID RELATED DISORDERS

ANTACIDS

Combinations and complexes of aluminium, calcium and magnesium compounds

ALUMINIUM HYDROXIDE + MAGNESIUM HYDROXIDE + MAGNESIUM TRISILICATE

2159P NP	aluminium hydroxide 250 mg/5 mL + magnesium hydroxide 120 mg/5 mL + magnesium trisilicate 120 mg/5 mL oral liquid, 500 mL	2	5	..	*18.04	19.19	Gastrogel	FM

ALUMINIUM HYDROXIDE WITH MAGNESIUM HYDROXIDE

2157M NP	ALUMINIUM HYDROXIDE with MAGNESIUM HYDROXIDE Oral suspension 200 mg-200 mg per 5 mL, 500 mL, 1	2	5	..	*18.04	19.19	Mylanta P	JT

DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)

H2-receptor antagonists

CIMETIDINE

Note

Helicobacter pylori eradication therapy should be considered prior to commencing initial treatment of peptic ulcer with this drug.

1158Y NP	cimetidine 400 mg tablet, 60	1	5	..	17.11	18.26	Magical 400	AF

FAMOTIDINE

Note

Helicobacter pylori eradication therapy should be considered prior to commencing initial treatment of peptic ulcer with this drug.

2487X NP	famotidine 20 mg tablet, 60	1	5	..	11.80	12.95	^a Ausfam 20	QA
							^a Chem mart Famotidine	CH
							^a Famotidine AN	EA
							^a Famotidine Sandoz	SZ
							^a GenRx Famotidine	GX
							^a Pamacid 20	AF

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
2488Y NP	famotidine 40 mg tablet, 30	1	5	..	11.80	12.95	^a Pepzan	GN
							^a Terry White Chemists Famotidine	TW
							^a Ausfam 40	QA
							^a Chem mart Famotidine	CH
							^a Famotidine AN	EA
							^a Famotidine Sandoz	SZ
							^a GenRx Famotidine	GX
							^a Pamacid 40	AF
							^a Pepzan	GN
							^a Terry White Chemists Famotidine	TW
NIZATIDINE								
Note								
Helicobacter pylori eradication therapy should be considered prior to commencing initial treatment of peptic ulcer with this drug.								
1505F NP	nizatidine 150 mg capsule, 60	1	5	..	18.77	19.92	^a Nizac	LN
				^B 5.32	24.09	19.92	^a Tacidine	AF
1504E NP	nizatidine 300 mg capsule, 30	1	5	..	18.77	19.92	^a Tazac	AS
							^a Nizac	LN
				^B 5.32	24.09	19.92	^a Tacidine	AF
							^a Tazac	AS
RANITIDINE								
Note								
Helicobacter pylori eradication therapy should be considered prior to commencing initial treatment of peptic ulcer with this drug.								
1978D NP,MW	ranitidine 150 mg tablet, 60	1	5	..	12.12	13.27	^a APO-Ranitidine	TX
							^a Ausran	QA
							^a Chem mart Ranitidine	CH
							^a GenRx Ranitidine	GX
							^a Rani 2	AF
							^a Ranitidine AN	EA
							^a Ranitidine Sandoz	SZ
							^a Ranoxyl	GN
							^a Terry White Chemists Ranitidine	TW
				^B 1.15	13.27	13.27	^a Ulcaid	RA
1937Y NP	ranitidine 150 mg tablet: effervescent, 30	2	5	..	*12.12	13.27	^a Zantac	AS
8162N NP	ranitidine 150 mg/10 mL oral liquid, 300 mL	2	5	..	*24.86	26.01	Zantac Syrup	AS
1977C NP	ranitidine 300 mg tablet, 30	1	5	..	12.12	13.27	^a APO-Ranitidine	TX
							^a Ausran	QA
							^a Chem mart Ranitidine	CH
							^a GenRx Ranitidine	GX
							^a Rani 2	AF
							^a Ranitidine GH	GQ
							^a Ranitidine Sandoz	SZ
							^a Ranoxyl	GN
							^a Terry White Chemists Ranitidine	TW
				^B 1.15	13.27	13.27	^a Zantac	AS

Proton pump inhibitors

ESOMEPRAZOLE

Restricted benefit

Maintenance of healed gastro-oesophageal reflux disease

Restricted benefit

Scleroderma oesophagus

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
<u>Restricted benefit</u> Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion							
<u>Note</u> No applications for increased maximum quantities will be authorised.							
8600P NP	esomeprazole 20 mg tablet: enteric, 30 tablets	1	5	..	25.37	26.52	^a Esomeprazole Apotex TX ^a Esomeprazole GxP AF ^a Esomeprazole RBX RA ^a Nexium AP
ESOMEPRAZOLE <u>Restricted benefit</u> Initial treatment of gastric ulcer							
<u>Note</u> Helicobacter pylori eradication therapy should be considered.							
<u>Note</u> No applications for increased maximum quantities and/or repeats will be authorised.							
8886Q NP	esomeprazole 20 mg tablet: enteric, 30 tablets	1	1	..	25.37	26.52	^a Esomeprazole Apotex TX ^a Esomeprazole GxP AF ^a Esomeprazole RBX RA ^a Nexium AP
ESOMEPRAZOLE <u>Authority required</u> Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion							
<u>Authority required</u> Scleroderma oesophagus							
<u>Note</u> Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
3401B NP	esomeprazole 40 mg tablet: enteric, 30 tablets	1	5	..	38.32	37.70	^a Esomeprazole Apotex TX ^a Esomeprazole GxP AF ^a Esomeprazole RBX RA ^a Nexium AP
ESOMEPRAZOLE <u>Restricted benefit</u> Healing of gastro-oesophageal reflux disease							
<u>Note</u> No applications for increased maximum quantities and/or repeats will be authorised.							
8601Q NP	esomeprazole 40 mg tablet: enteric, 30 tablets	1	1	..	38.32	37.70	^a Esomeprazole Apotex TX ^a Esomeprazole GxP AF ^a Esomeprazole RBX RA ^a Nexium AP
LANSOPRAZOLE <u>Restricted benefit</u> Gastro-oesophageal reflux disease							
<u>Restricted benefit</u> Scleroderma oesophagus							
8198L NP	lansoprazole 15 mg capsule: enteric, 30	1	5	..	13.95	15.10	Zopral AF
9331D NP	lansoprazole 15 mg tablet: orally disintegrating, 28 tablets	1	5	..	13.44	14.59	^a Lansoprazole ODT GH GQ ^a Zopral ODT AF ^a Zoton FasTabs PF

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
<u>Restricted benefit</u>								
Initial treatment of peptic ulcer								
<u>Note</u>								
Helicobacter pylori eradication therapy should be considered.								
No applications for increased repeats will be authorised.								
<u>Note</u>								
Pharmaceutical benefits that have the form lansoprazole capsule 30 mg and pharmaceutical benefits that have the form lansoprazole tablet 30 mg (orally disintegrating) are equivalent for the purposes of substitution.								
2240X NP	lansoprazole 30 mg capsule: enteric, 28	1	1	..	18.75	19.90	^a APO-Lansoprazole	TX
							^a Lanzopran	RA
							^a Zopral	AF
9477T NP	lansoprazole 30 mg tablet: orally disintegrating, 28 tablets	1	1	..	18.75	19.90	^a Lansoprazole ODT GH	GQ
							^a Zopral ODT	AF
							^a Zoton FasTabs	PF
LANSOPRAZOLE								
<u>Restricted benefit</u>								
Gastro-oesophageal reflux disease								
<u>Restricted benefit</u>								
Scleroderma oesophagus								
<u>Note</u>								
Pharmaceutical benefits that have the form lansoprazole capsule 30 mg and pharmaceutical benefits that have the form lansoprazole tablet 30 mg (orally disintegrating) are equivalent for the purposes of substitution.								
2241Y NP	lansoprazole 30 mg capsule: enteric, 28	1	5	..	18.75	19.90	^a APO-Lansoprazole	TX
							^a Lanzopran	RA
							^a Zopral	AF
9478W NP	lansoprazole 30 mg tablet: orally disintegrating, 28 tablets	1	5	..	18.75	19.90	^a Zopral ODT	AF
							^a Zoton FasTabs	PF
OMEPRAZOLE								
<u>Restricted benefit</u>								
Gastro-oesophageal reflux disease								
<u>Restricted benefit</u>								
Scleroderma oesophagus								
<u>Restricted benefit</u>								
Zollinger-Ellison syndrome								
8332M NP	omeprazole 10 mg tablet: enteric, 30 tablets	1	5	..	11.54	12.69	Losec Tablets	AP
OMEPRAZOLE								
<u>Restricted benefit</u>								
Peptic ulcer								
Treatment Phase: Initial treatment								
<u>Note</u>								
Helicobacter pylori eradication therapy should be considered.								
<u>Note</u>								
Pharmaceutical benefits that have the forms omeprazole tablet 20 mg, omeprazole capsule 20 mg and omeprazole tablet 20 mg (as magnesium) are equivalent for the purposes of substitution.								
<u>Note</u>								
No increase in the maximum number of repeats may be authorised.								
1326T NP	omeprazole 20 mg capsule, 30	1	1	..	13.53	14.68	^a APO-Omeprazole	TX
							^a Maxor	AF
							^a Omeprazole Sandoz	HX
							^a Omepro-GA	GN
							^a Pemzo	QA
							^a Pharmacor Omeprazole	CR

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
8331L NP	omeprazole 20 mg tablet: enteric, 30 tablets	1	1	..	13.53	14.68	a 20 Probitor	SZ
							a APO-Omeprazole	TX
							a Chem mart Omeprazole	CH
							a Meprazol	SZ
							a Omeprazole AN	EA
							a Omeprazole-GA	GN
							a Omeprazole generichealth	GQ
							a Omeprazole RBX	RA
							a Ozmep	ZP
							a Terry White Chemists Omeprazole	TW
9109K NP	omeprazole 20 mg tablet: enteric, 30 tablets	1	1	..	13.53	14.68	a Acimax Tablets	AL
							a Omepral	TX
							a Omeprazole Sandoz	SZ
							a Losec Tablets	AP
							B2.48	16.01
OMEPRAZOLE								
<u>Restricted benefit</u>								
Gastro-oesophageal reflux disease								
<u>Restricted benefit</u>								
Scleroderma oesophagus								
<u>Restricted benefit</u>								
Zollinger-Ellison syndrome								
<u>Note</u>								
Pharmaceutical benefits that have the forms omeprazole tablet 20 mg, omeprazole capsule 20 mg and omeprazole tablet 20 mg (as magnesium) are equivalent for the purposes of substitution.								
1327W NP	omeprazole 20 mg capsule, 30	1	5	..	13.53	14.68	a APO-Omeprazole	TX
							a Maxor	AF
							a Omeprazole Sandoz	HX
							a Omepro-GA	GN
							a Pemzo	QA
							a Pharmacor Omeprazole 20	CR
8333N NP	omeprazole 20 mg tablet: enteric, 30 tablets	1	5	..	13.53	14.68	a Probitor	SZ
							a APO-Omeprazole	TX
							a Chem mart Omeprazole	CH
							a Meprazol	SZ
							a Omeprazole AN	EA
							a Omeprazole-GA	GN
							a Omeprazole generichealth	GQ
							a Omeprazole RBX	RA
							a Ozmep	ZP
							a Terry White Chemists Omeprazole	TW
9110L NP	omeprazole 20 mg tablet: enteric, 30 tablets	1	5	..	13.53	14.68	a Acimax Tablets	AL
							a Omepral	TX
							a Omeprazole Sandoz	SZ
							a Losec Tablets	AP
							B2.48	16.01

PANTOPRAZOLE

Restricted benefit

Gastro-oesophageal reflux disease

Restricted benefit

Scleroderma oesophagus

Restricted benefit

Zollinger-Ellison syndrome

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
8399C NP	pantoprazole 20 mg tablet: enteric, 30 tablets	1	5	..	9.08	10.23	a APO-Pantoprazole	TX
							a Chem mart	CH
							a Pantoprazole	
							a I-Pantoprazole	CR
							a Ozpan	RA
							a Panthron	ER
							a Panto	TK
							a Pantofast 20	RZ
							a Pantoprazole AN	EA
							a Pantoprazole-GA	GN
							a Pantoprazole	GQ
							a generichealth	
							a Pantoprazole Sandoz	SZ
							a Salpraz	AF
							a Somac	NQ
							a Sozol	QA
							a Terry White Chemists	TW
							a Pantoprazole	
							a Torzole 20	VN
9424B NP	pantoprazole 40 mg granules: enteric-coated, 30 sachets	1	5	..	31.05	32.20	a Somac	NQ
8008L NP	pantoprazole 40 mg tablet: enteric, 30 tablets	1	5	..	11.54	12.69	a APO-Pantoprazole	TX
							a Chem mart	CH
							a Pantoprazole	
							a I-Pantoprazole	CR
							a Ozpan	RA
							a Panthron	ER
							a Panto	TK
							a Pantofast 40	RZ
							a Pantoprazole Actavis	GN
							a Pantoprazole AN	EA
							a Pantoprazole-GA	UA
							a Pantoprazole	GQ
							a generichealth	
							a Pantoprazole Sandoz	SZ
							a Salpraz	AF
							a Somac	NQ
							a Sozol	QA
							a Terry White Chemists	TW
							a Pantoprazole	
							a Topra 40	DO
							a Torzole 40	VN

PANTOPRAZOLE

Restricted benefit

Initial treatment of peptic ulcer

Note

Helicobacter pylori eradication therapy should be considered.

Note

No applications for increased repeats will be authorised.

9423Y NP	pantoprazole 40 mg granules: enteric-coated, 30 sachets	1	2	..	31.05	32.20	Somac	NQ
8007K NP	pantoprazole 40 mg tablet: enteric, 30 tablets	1	2	..	11.54	12.69	a APO-Pantoprazole	TX
							a Chem mart	CH
							a Pantoprazole	
							a I-Pantoprazole	CR
							a Ozpan	RA
							a Panthron	ER
							a Panto	TK
							a Pantofast 40	RZ
							a Pantoprazole Actavis	GN
							a Pantoprazole AN	EA

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							a Pantoprazole-GA	UA
							a Pantoprazole generichealth	GQ
							a Pantoprazole Sandoz	SZ
							a Salpraz	AF
							a Somac	NQ
							a Sozol	QA
							a Terry White Chemists Pantoprazole	TW
							a Topra 40	DO
							a Torzole 40	VN
	RABEPRAZOLE							
	<u>Restricted benefit</u>							
	Gastro-oesophageal reflux disease							
	<u>Restricted benefit</u>							
	Scleroderma oesophagus							
8507R NP	rabeprazole sodium 10 mg tablet: enteric, 28	1	5	..	15.10	16.25	a APO-Rabeprazole	TX
							a Chem mart Rabeprazole	CH
							a Pariet	JC
							a Parzol 10	ZP
							a Prabez	AF
							a Rabeprazole AN	EA
							a Rabeprazole-DRLA	RZ
							a Rabeprazole-GA	GN
							a Rabeprazole generichealth	GQ
							a Rabeprazole Sandoz	SZ
							a Razit 10	DO
							a Terry White Chemists Rabeprazole	TW
8508T NP	rabeprazole sodium 20 mg tablet: enteric, 30	1	5	..	15.10	16.25	a APO-Rabeprazole	TX
							a Chem mart Rabeprazole	CH
							a Pariet	JC
							a Parzol 20	ZP
							a Prabez	AF
							a Rabeprazole Actavis 20	UA
							a Rabeprazole AN	EA
							a Rabeprazole-DRLA	RZ
							a Rabeprazole generichealth	GQ
							a Rabeprazole RBX	RA
							a Rabeprazole Sandoz	SZ
							a Razit 20	DO
							a Terry White Chemists Rabeprazole	TW
	RABEPRAZOLE							
	<u>Restricted benefit</u>							
	Initial treatment of peptic ulcer							
	<u>Note</u>							
	Helicobacter pylori eradication therapy should be considered.							
	<u>Note</u>							
	No applications for increased repeats will be authorised.							
8509W NP	rabeprazole sodium 20 mg tablet: enteric, 30	1	2	..	15.10	16.25	a APO-Rabeprazole	TX
							a Chem mart Rabeprazole	CH
							a Pariet	JC
							a Parzol 20	ZP
							a Prabez	AF
							a Rabeprazole Actavis 20	UA
							a Rabeprazole AN	EA

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							^a Rabeprazole-DRLA	RZ
							^a Rabeprazole generichealth	GQ
							^a Rabeprazole RBX	RA
							^a Rabeprazole Sandoz	SZ
							^a Razit 20	DO
							^a Terry White Chemists Rabeprazole	TW

Combinations for eradication of *Helicobacter pylori*

ESOMEPRAZOLE (&) CLARITHROMYCIN (&) AMOXICYLLIN

Restricted benefit

Eradication of *Helicobacter pylori* associated with peptic ulcer disease

8738X NP	esomeprazole 20 mg tablet: enteric [14 tablets] (&) clarithromycin 500 mg tablet [14 tablets] (&) amoxicillin 500 mg capsule [28 capsules], 1 pack	1	..	..	50.23	37.70	Nexium Hp7	AP

Other drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD)

ALGINATE SODIUM + CALCIUM CARBONATE + BICARBONATE

2014B NP	alginate sodium 500 mg/10 mL + calcium carbonate 160 mg/10 mL + sodium bicarbonate 267 mg/10 mL oral liquid, 500 mL	2	5	..	*15.02	16.17	Gaviscon P	RC

SUCRALFATE

2055E NP	sucralfate 1 g tablet, 120	1	2	..	23.84	24.99	^a Ulcyte	AF
				^b 2.30	26.14	24.99	^a Carafate	AS

DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

BELLADONNA AND DERIVATIVES, PLAIN

Belladonna alkaloids, tertiary amines

ATROPINE

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1089H NP	ATROPINE Injection 600 micrograms in 1 mL, 10	1	1	..	20.88	22.03	Pfizer Australia Pty Ltd	PF

ATROPINE

5022H DP	ATROPINE Injection 600 micrograms in 1 mL, 10	1	..	..	20.88	22.03	Pfizer Australia Pty Ltd	PF

PROPULSIVES

Propulsives

DOMPERIDONE

1347X NP	domperidone 10 mg tablet, 25	1	..	..	9.23	10.38	Motilium	JC

METOCLOPRAMIDE

1207M NP,MW	metoclopramide hydrochloride 10 mg tablet, 25	1	..	..	8.26	9.41	^a APO-Metoclopramide	TX
							^a Metoclopramide Actavis	GN
							^a Metoclopramide AN	EA
							^a Pramin	AF
				^b 2.54	10.80	9.41	^a Maxolon	IA
5151D DP	metoclopramide hydrochloride 10 mg tablet, 25	1	..	..	8.26	9.41	^a APO-Metoclopramide	TX
							^a Metoclopramide Actavis	GN
							^a Metoclopramide AN	EA
							^a Pramin	AF

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
				^b 2.54	10.80	9.41	^a Maxolon	IA
1206L NP, MW	metoclopramide hydrochloride 10 mg/2 mL injection, 10 x 2 mL ampoules	1	..	..	13.33	14.48	Maxolon	IA
5153F DP	metoclopramide hydrochloride 10 mg/2 mL injection, 10 x 2 mL ampoules	1	..	..	13.33	14.48	Maxolon	IA

ANTIEMETICS AND ANTINAUSEANTS

ANTIEMETICS AND ANTINAUSEANTS *Serotonin (5HT₃) antagonists*

GRANISETRON

Restricted benefit

Nausea and vomiting

Clinical criteria:

The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.

8728J NP	granisetron 2 mg tablet, 1	2	..	..	*29.74	30.89	Kytril	RO

GRANISETRON

Authority required (STREAMLINED)

4102

Nausea and vomiting

Clinical criteria:

The condition must be associated with radiotherapy being used to treat malignancy.

8873B NP	granisetron 2 mg tablet, 5	1	1	..	61.69	37.70	Kytril	RO

GRANISETRON

Restricted benefit

Nausea and vomiting

Clinical criteria:

The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.

8729K NP	granisetron 3 mg/3 mL injection, 1 x 3 mL ampoule	1	..	..	11.68	12.83	^a Granisetron-AFT	AE
							^a Granisetron Kabi	PK
							^a Kytril	RO

GRANISETRON

Authority required (STREAMLINED)

4092

Nausea and vomiting

Clinical criteria:

The condition must be associated with radiotherapy being used to treat malignancy.

8730L NP	granisetron 3 mg/3 mL injection, 1 x 3 mL ampoule	1	..	..	11.68	12.83	^a Granisetron-AFT	AE
							^a Granisetron Kabi	PK
							^a Kytril	RO

ONDANSETRON

Authority required (STREAMLINED)

3611

Management of nausea and vomiting associated with radiotherapy being used to treat malignancy

Note

Pharmaceutical benefits that have the form ondansetron tablet (orally disintegrating) 4 mg and pharmaceutical benefits that have the form ondansetron wafer 4 mg are equivalent for the purposes of substitution.

5472B NP	ONDANSETRON Tablet (orally disintegrating) 4 mg, 10	1	1	..	26.85	28.00	^a Ondansetron AN ODT	EA

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
8412R NP	ondansetron 4 mg wafer, 10	1	1	..	26.85	28.00	^a Ondansetron ODT-DRLA	RZ
							^a Onsetron ODT 4	GN
							^a Zilfojim ODT 4	DO
							^a Ondaz Zydis	SZ
							^a Zofran Zydis	AS

ONDANSETRON

Restricted benefit

Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle

Note

Pharmaceutical benefits that have the form ondansetron tablet (orally disintegrating) 4 mg and pharmaceutical benefits that have the form ondansetron wafer 4 mg are equivalent for the purposes of substitution.

5470X NP	ONDANSETRON Tablet (orally disintegrating) 4 mg, 4	1	..	..	14.80	15.95	^a Ondansetron AN ODT	EA
							^a Ondansetron ODT-DRLA	RZ
8410P NP	ondansetron 4 mg wafer, 4	1	..	..	14.80	15.95	^a Onsetron ODT 4	GN
							^a Ondaz Zydis	SZ
							^a Zofran Zydis	AS

ONDANSETRON

Authority required (STREAMLINED)

3611

Management of nausea and vomiting associated with radiotherapy being used to treat malignancy

Note

Pharmaceutical benefits that have the form ondansetron tablet (orally disintegrating) 8 mg and pharmaceutical benefits that have the form ondansetron wafer 8 mg are equivalent for the purposes of substitution.

5473C NP	ONDANSETRON Tablet (orally disintegrating) 8 mg, 10	1	1	..	38.22	37.70	^a Ondansetron AN ODT	EA
							^a Ondansetron ODT-DRLA	RZ
							^a Onsetron ODT 8	GN
							^a Zilfojim ODT 8	DO
8413T NP	ondansetron 8 mg wafer, 10	1	1	..	38.22	37.70	^a Ondaz Zydis	SZ
							^a Zofran Zydis	AS

ONDANSETRON

Restricted benefit

Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle

Note

Pharmaceutical benefits that have the form ondansetron tablet (orally disintegrating) 8 mg and pharmaceutical benefits that have the form ondansetron wafer 8 mg are equivalent for the purposes of substitution.

5471Y NP	ONDANSETRON Tablet (orally disintegrating) 8 mg, 4	1	..	..	19.35	20.50	^a Ondansetron AN ODT	EA
							^a Ondansetron ODT-DRLA	RZ
							^a Onsetron ODT 8	GN
8411Q NP	ondansetron 8 mg wafer, 4	1	..	..	19.35	20.50	^a Ondaz Zydis	SZ
							^a Zofran Zydis	AS

ONDANSETRON

Authority required (STREAMLINED)

3611

Management of nausea and vomiting associated with radiotherapy being used to treat malignancy

1594X NP	ondansetron 4 mg tablet, 10	1	1	..	26.85	28.00	^a APO-Ondansetron	TX
							^a Ondansetron AN	EA
							^a Ondansetron-DRLA	RZ
							^a Ondaz	SZ

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
1596B NP	ondansetron 4 mg/2 mL injection, 1 x 2 mL ampoule	1	..	..	7.48	8.63	a Onsetron 4	ZP
							a Zilfojim 4	DO
							a Zofran	AS
							a Ondansetron	AF
							Alphapharm	
							a Ondansetron-Claris	AE
							a Ondansetron Kabi	PK
8233H NP	ondansetron 4 mg/5 mL oral liquid, 50 mL	1	1	..	102.30	37.70	a Ondaz	SZ
							a Onsetron	ZP
1595Y NP	ondansetron 8 mg tablet, 10	1	1	..	38.22	37.70	a Zofran syrup 50 mL	AS
							a APO-Ondansetron	TX
							a Ondansetron AN	EA
							a Ondansetron-DRLA	RZ
							a Ondaz	SZ
							a Onsetron 8	ZP
							a Zilfojim 8	DO
1597C NP	ondansetron 8 mg/4 mL injection, 1 x 4 mL ampoule	1	..	..	7.92	9.07	a Zofran	AS
							a Ondansetron	AF
							Alphapharm	
							a Ondansetron-Claris	AE
							a Ondansetron Kabi	PK
							a Ondaz	SZ
							a Onsetron	ZP

ONDANSETRON

Restricted benefit

Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle

8224W NP	ondansetron 4 mg tablet, 4	1	..	..	14.80	15.95	a APO-Ondansetron	TX
							a Ondansetron AN	EA
							a Ondansetron-DRLA	RZ
							a Ondaz	SZ
							a Onsetron 4	ZP
8226Y NP	ondansetron 4 mg/2 mL injection, 1 x 2 mL ampoule	1	..	..	7.48	8.63	a Zofran	AS
							a Ondansetron	AF
							Alphapharm	
							a Ondansetron-Claris	AE
							a Ondansetron Kabi	PK
9441X NP	ondansetron 4 mg/5 mL oral liquid, 50 mL	1	..	..	102.30	37.70	a Ondaz	SZ
							a Onsetron	ZP
8225X NP	ondansetron 8 mg tablet, 4	1	..	..	19.35	20.50	a Zofran syrup 50 mL	AS
							a APO-Ondansetron	TX
8227B NP	ondansetron 8 mg/4 mL injection, 1 x 4 mL ampoule	1	..	..	7.92	9.07	a Ondansetron AN	EA
							a Ondansetron-DRLA	RZ
							a Ondaz	SZ
							a Onsetron 8	ZP
							a Zofran	AS
							a Ondansetron	AF
							Alphapharm	
							a Ondansetron-Claris	AE
							a Ondansetron Kabi	PK
							a Ondaz	SZ
							a Onsetron	ZP

PALONOSETRON

Restricted benefit

Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration

Note

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	No applications for increased maximum quantities will be authorised. Palonosetron is not PBS-subsidised for administration with oral 5-HT3 antagonists.							
5295Q NP	palonosetron 250 microgram/5 mL injection, 1 x 5 mL vial	1	..	..	48.20	37.70	Aloxi	TS
TROPISETRON								
<u>Restricted benefit</u>								
Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.								
Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle								
2746M NP	tropisetron 5 mg/5 mL injection, 1 x 5 mL ampoule	1	..	..	14.03	15.18	Tropisetron-AFT	AE

Other antiemetics

APREPITANT

Authority required (STREAMLINED)

4211

Nausea and vomiting

Clinical criteria:

The condition must be associated with cytotoxic chemotherapy being used to treat malignancy,

AND

The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone,

AND

Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following agents: altretamine; carmustine; cisplatin when a single dose constitutes a cycle of chemotherapy; cyclophosphamide at a dose of 1500 mg per square metre per day or greater; dacarbazine; procarbazine when a single dose constitutes a cycle of chemotherapy; streptozocin.

No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.

Authority required (STREAMLINED)

4215

Nausea and vomiting

Clinical criteria:

The condition must be associated with cytotoxic chemotherapy being used to treat breast cancer,

AND

The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone,

AND

Patient must be scheduled to be co-administered cyclophosphamide and an anthracycline.

No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.

Authority required (STREAMLINED)

4213

Nausea and vomiting

Clinical criteria:

The condition must be associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy,

AND

The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle,

AND

Patient must have had a prior episode of chemotherapy induced nausea or vomiting,

AND

Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following intravenous chemotherapy agents: arsenic trioxide; azacitidine; carboplatin; cyclophosphamide at a dose of less than 1500 mg per square metre per day; cytarabine at a dose of greater than 1 g per square metre per day; dactinomycin; daunorubicin; doxorubicin; epirubicin; fotemustine; idarubicin; ifosfamide; irinotecan; melphalan; methotrexate at a dose of 250 mg to 1 g per square metre; oxaliplatin; raltitrexed.

No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.

Concomitant use of a 5HT3 antagonist should not occur with aprepitant on days 2 and 3 of any chemotherapy cycle.

Note

Aprepitant is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy.

Note

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
No increase in the maximum quantity or number of units may be authorised.								
Note								
No increase in the maximum number of repeats may be authorised.								
2518M NP	aprepitant 165 mg capsule, 1	1	5	..	138.13	37.70	Emend	MK
PROCHLORPERAZINE								
Caution								
Prochlorperazine may be associated with parkinsonism and tardive dyskinesia and should be used for short-term treatment only.								
Note								
As prochlorperazine may be associated with parkinsonism and tardive dyskinesia it should be used for short-term treatment only. However, authorities for increased maximum quantities and/or repeats of prochlorperazine tablets will be granted for the treatment of emesis associated with malignant disease.								
2895J NP	prochlorperazine maleate 25 mg suppository, 5	1	2	..	20.27	21.42	Stemetil	SW
2893G NP	prochlorperazine maleate 5 mg tablet, 25	1	..	..	8.19	9.34	^a APO-Prochlorperazine	TX
							^a Pharmacor Prozine 5	CR
							^a ProCalm	QA
							^a Prochlorperazine AN	EA
							^a Prochlorperazine-GA	GN
							^a Prochlorperazine GH	GQ
							^a Stemetil	AV
				^b 2.70	10.89	9.34	^a Stemetil	SW
2369Q NP	prochlorperazine mesylate 12.5 mg/mL injection, 10 x 1 mL ampoules	1	..	..	17.89	19.04	Stemetil	SW
PROCHLORPERAZINE								
Caution								
Prochlorperazine may be associated with parkinsonism and tardive dyskinesia and should be used for short-term treatment only.								
5208D DP	prochlorperazine maleate 25 mg suppository, 5	1	..	..	20.27	21.42	Stemetil	SW
5205Y DP	prochlorperazine maleate 5 mg tablet, 25	1	..	..	8.19	9.34	^a APO-Prochlorperazine	TX
							^a Pharmacor Prozine 5	CR
							^a ProCalm	QA
							^a Prochlorperazine AN	EA
							^a Prochlorperazine-GA	GN
							^a Prochlorperazine GH	GQ
							^a Stemetil	AV
				^b 2.70	10.89	9.34	^a Stemetil	SW
5206B DP	prochlorperazine mesylate 12.5 mg/mL injection, 10 x 1 mL ampoules	1	..	..	17.89	19.04	Stemetil	SW
PROMETHAZINE								
3374N DP	promethazine hydrochloride 50 mg/2 mL injection, 5 x 2 mL ampoules	2	..	..	*30.58	31.73	Hospira Pty Limited	HH

BILE AND LIVER THERAPY

BILE THERAPY

Bile acid preparations

URSODEOXYCHOLIC ACID

Authority required (STREAMLINED)

1700

Primary biliary cirrhosis

Note

Not for use in the treatment of sclerosing cholangitis or cholelithiasis.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8448P	ursodeoxycholic acid 250 mg capsule,	2	2	..	*317.22	37.70	^a Ursfolk	OA

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
NP	100							
							^a Ursosan	BZ

DRUGS FOR CONSTIPATION

DRUGS FOR CONSTIPATION

Contact laxatives

BISACODYL

Restricted benefit

Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function

Restricted benefit

Patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities

Restricted benefit

For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult

Restricted benefit

Patients receiving palliative care

Restricted benefit

Terminal malignant neoplasia

Restricted benefit

Anorectal congenital abnormalities

Restricted benefit

Megacolon

1260H NP	bisacodyl 10 mg suppository, 10	3	5	..	*21.28	22.43	^a	Petrus Bisacodyl Suppositories	PP
				^b 1.50	*22.78	22.43	^a	Dulcolax	BY
1258F NP	bisacodyl 10 mg suppository, 12	3	4	..	*18.67	19.82		Petrus Bisacodyl Suppositories	PP
1259G NP	bisacodyl 5 mg tablet: enteric, 200 tablets	1	2	..	14.45	15.60		Bisalax	AS
								Lax-Tab	AE

Bulk-forming laxatives

RHAMNUS FRANGULA + STERCULIA

Restricted benefit

Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function

Restricted benefit

Patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities

Restricted benefit

For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult

Restricted benefit

Patients receiving palliative care

Restricted benefit

Terminal malignant neoplasia

Restricted benefit

Anorectal congenital abnormalities

Restricted benefit

Megacolon

1104D NP	rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g	±1	1	..	26.71	27.86		Normacol Plus	NE

Osmotically acting laxatives

LACTULOSE

Restricted benefit

Hepatic coma or precoma (chronic porto-systemic encephalopathy)

Restricted benefit

Constipation in patients with malignant neoplasia

3064G NP	LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1	±1	5	..	10.70	11.85	^a	Genlac	QA
				^b 0.89	11.59	11.85	^a	Actilax	AF
							^a	Dulose	FM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	MACROGOL-3350 <u>Restricted benefit</u> Constipation Clinical criteria: Patient must have malignant neoplasia. <u>Restricted benefit</u> Constipation Clinical criteria: Patient must be paraplegic, quadriplegic or have severe neurogenic impairment of bowel function, AND The condition must be unresponsive to other oral therapies. <u>Restricted benefit</u> Constipation Clinical criteria: Patient must be receiving palliative care. <u>Restricted benefit</u> Chronic constipation Clinical criteria: The condition must be inadequately controlled with first line interventions such as bulk-forming agents. <u>Restricted benefit</u> Faecal impaction Clinical criteria: The condition must be inadequately controlled with first line interventions such as bulk-forming agents. Note Pharmaceutical benefits that have the form macrogol-3350 1 g/g oral liquid: powder for, 510 g and pharmaceutical benefits that have the form macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets are equivalent for the purposes of substitution.						
2373X NP	macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets	±1	5	..	18.57	19.72 ^a	Herron ClearLax ON
3416T NP	macrogol-3350 1 g/g oral liquid: powder for, 510 g	±1	5	..	18.57	19.72 ^a	OsmoLax KY
	MACROGOL-3350 + SODIUM CHLORIDE + POTASSIUM CHLORIDE + BICARBONATE <u>Restricted benefit</u> Constipation Clinical criteria: Patient must have malignant neoplasia. <u>Restricted benefit</u> Constipation Clinical criteria: Patient must be paraplegic, quadriplegic or have severe neurogenic impairment of bowel function, AND The condition must be unresponsive to other oral therapies. <u>Restricted benefit</u> Constipation Clinical criteria: Patient must be receiving palliative care. <u>Restricted benefit</u> Chronic constipation Clinical criteria: The condition must be inadequately controlled with first line interventions such as bulk-forming agents. <u>Restricted benefit</u> Faecal impaction Clinical criteria: The condition must be inadequately controlled with first line interventions such as bulk-forming agents.						

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
8612G NP	macrogol-3350 13.12 g + sodium chloride 350.7 mg + potassium chloride 46.6 mg (0.63 mmol potassium) + sodium bicarbonate 178.5 mg solution, 30 sachets	1	5	..	18.57	19.72	^a APO-MACROGOL plus ELECTROLYTES	TX
							^a LaxaCon	GN
							^a lax-sachets	AE
							^a Macrovic	QA
							^a Molaxole	HM
							^a Movicol	NE
10126Y NP	macrogol-3350 13.12 g/25 mL + sodium chloride 350.7 mg/25 mL + potassium chloride 46.6 mg/25 mL (0.63 mmol/25 mL potassium) + sodium bicarbonate 178.5 mg/25 mL oral liquid, 500 mL	2	5	..	*22.52	23.67	Movicol Liquid	NE

Enemas

BISACODYL

Restricted benefit

Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function

Restricted benefit

Patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities

Restricted benefit

For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult

Restricted benefit

Patients receiving palliative care

Restricted benefit

Terminal malignant neoplasia

Restricted benefit

Anorectal congenital abnormalities

Restricted benefit

Megacolon

1263L NP	bisacodyl 10 mg/5 mL enema, 25 x 5 mL	1	2	..	38.28	37.70	Bisalax	AS

SORBITOL + CITRATE + LAURYL SULFOACETATE SODIUM

Restricted benefit

Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function

Restricted benefit

Patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities

Restricted benefit

For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult

Restricted benefit

Patients receiving palliative care

Restricted benefit

Terminal malignant neoplasia

Restricted benefit

Anorectal congenital abnormalities

Restricted benefit

Megacolon

2091C NP	sorbitol 3.125 g/5 mL + citrate sodium dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 12 x 5 mL	2	2	..	*32.62	33.77	^a Micolette	AE
							^a Microlax	JT

Other drugs for constipation

GLYCEROL

Restricted benefit

Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	<u>Restricted benefit</u> Patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities							
	<u>Restricted benefit</u> For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult							
	<u>Restricted benefit</u> Patients receiving palliative care							
	<u>Restricted benefit</u> Terminal malignant neoplasia							
	<u>Restricted benefit</u> Anorectal congenital abnormalities							
	<u>Restricted benefit</u> Megacolon							
2556M NP	glycerol 1.4 g suppository, 12	3	5	..	*21.55	22.70	Petrus Pharmaceuticals Pty Ltd	PP
2557N NP	glycerol 2.8 g suppository, 12	3	5	..	*22.15	23.30	Petrus Pharmaceuticals Pty Ltd	PP
2555L NP	glycerol 700 mg suppository, 12	3	5	..	*21.10	22.25	Petrus Pharmaceuticals Pty Ltd	PP

ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS

INTESTINAL ANTIINFECTIVES

Antibiotics

NYSTATIN

1699K NP	nystatin 500 000 international units capsule, 50	1	..	..	18.32	19.47	Nilstat	QA
3345C DP	nystatin 500 000 international units capsule, 50	1	..	..	18.32	19.47	Nilstat	QA
1696G NP	nystatin 500 000 international units tablet, 50	1	..	..	18.32	19.47	Nilstat	QA
3342X DP	nystatin 500 000 international units tablet, 50	1	..	..	18.32	19.47	Nilstat	QA

RIFAXIMIN

Authority required

Prevention of hepatic encephalopathy

Clinical criteria:

The treatment must be in combination with lactulose, if lactulose is tolerated,

AND

Patient must have had prior episodes of hepatic encephalopathy.

Treatment criteria:

Must be treated by a gastroenterologist or hepatologist or in consultation with a gastroenterologist or hepatologist.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

10001J	rifaximin 550 mg tablet, 56	1	5	..	495.10	37.70	Xifaxan	NE

VANCOMYCIN

Authority required

Antibiotic associated pseudomembranous colitis due to Clostridium difficile which is unresponsive to metronidazole

Authority required

Antibiotic associated pseudomembranous colitis due to Clostridium difficile where there is intolerance to metronidazole

Note

Metronidazole has similar efficacy to vancomycin but may have less selective pressure to vancomycin resistant enterococci and is therefore the preferred treatment.

3113W	vancomycin 125 mg capsule, 20	2	..	..	*232.60	37.70	Vancocin	AS
3114X	vancomycin 250 mg capsule, 20	2	..	..	*440.38	37.70	Vancocin	AS

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

ELECTROLYTES WITH CARBOHYDRATES

Oral rehydration salt formulations

SODIUM CHLORIDE + POTASSIUM CHLORIDE + GLUCOSE MONOHYDRATE + CITRATE

Note

Each sachet contains sodium chloride 470 mg, potassium chloride 300 mg, sodium acid citrate 530 mg and glucose 3.56 g.

3196F NP	sodium chloride 470 mg + potassium chloride 300 mg + glucose monohydrate 3.56 g + sodium acid citrate 530 mg oral liquid: powder for, 10 x 4.9 g sachets	\$1	..	..	13.25	14.40	^a O.R.S.	AS
							^a Repalyte New Formulation	SW
							^a restore O.R.S.	GN

ANTIPROPULSIVES

Antipropulsives

DIPHENOXYLATE + ATROPINE SULFATE

2501P NP	diphenoxylate hydrochloride 2.5 mg + atropine sulfate 25 microgram tablet, 20	1	..	..	8.81	9.96	^a Lofenoxal	IA
				^b 1.73	10.54	9.96	^a Lomotil	IV

LOPERAMIDE

1571Q NP	loperamide hydrochloride 2 mg capsule, 12	1	..	..	8.47	9.62	^a Gastrex	CR
							^a Gastro-Stop Loperamide	AS
				^b 0.75	9.22	9.62	^a Imodium	JT

INTESTINAL ANTIINFLAMMATORY AGENTS

Corticosteroids acting locally

BUDESONIDE

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

10034D NP	budesonide 2mg/application enema, 2 x 14 applications	1	3	..	211.65	37.70	Budenofalk	OA

HYDROCORTISONE ACETATE

Restricted benefit

Proctitis

Restricted benefit

Ulcerative colitis

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1502C NP	hydrocortisone acetate 10% (100 mg/g) enema, 21.1 g	2	3	..	*40.78	37.70	Colifoam	HM

PREDNISOLONE SODIUM PHOSPHATE

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1920C NP	prednisolone (as sodium phosphate) 20 mg/100 mL enema, 7 x 100 mL	4	3	..	*211.68	37.70	Predsol	QA

PREDNISOLONE SODIUM PHOSPHATE

Restricted benefit

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Proctitis							
	<u>Restricted benefit</u>							
	Ulcerative colitis							
	<u>Note</u>							
	Continuing Therapy Only:							
	For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
2554K NP	prednisolone (as sodium phosphate) 5 mg suppository, 10	3	3	..	*42.04	37.70	Predsol	QA
	<i>Aminosalicylic acid and similar agents</i>							
	BALSALAZIDE							
	<u>Authority required (STREAMLINED)</u>							
	4824							
	Ulcerative colitis							
	Clinical criteria:							
	Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR							
	Patient must be intolerant to sulfasalazine.							
	<u>Note</u>							
	Not for the treatment of Crohn disease							
	<u>Note</u>							
	Continuing Therapy Only:							
	For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
8845M NP	balsalazide sodium 750 mg capsule, 180	1	5	..	125.19	37.70	Colazide	PK
	MESALAZINE							
	<u>Authority required (STREAMLINED)</u>							
	4824							
	Ulcerative colitis							
	Clinical criteria:							
	Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR							
	Patient must be intolerant to sulfasalazine.							
	<u>Note</u>							
	Not for the treatment of Crohn disease							
	<u>Note</u>							
	Continuing Therapy Only:							
	For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
8599N NP	mesalazine 1 g granules: modified release, 100 x 1 g sachets	1	5	..	279.97	37.70	Salofalk	OA
9353G NP	mesalazine 1.2 g tablet: modified release, 60 tablets	1	5	..	221.33	37.70	Mezavant	ZI
9206M NP	mesalazine 1.5 g granules, 60 x 1.5 g sachets	1	5	..	245.26	37.70	Salofalk	OA
10257W NP	mesalazine 3 g granules, 30 sachets	1	5	..	245.26	37.70	Salofalk	OA
10254Q NP	mesalazine 4 g granules: modified release, 30 sachets	1	5	..	312.64	37.70	Pentasa	FP
8598M NP	mesalazine 500 mg granules, 100 x 500 mg sachets	2	5	..	*297.78	37.70	Salofalk	OA

MESALAZINE

Authority required (STREAMLINED)

4873

Ulcerative colitis

Clinical criteria:

Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR

Patient must be intolerant to sulfasalazine.

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
<u>Authority required (STREAMLINED)</u>								
4896								
Crohn disease								
Clinical criteria:								
Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR								
Patient must be intolerant to sulfasalazine.								
<u>Note</u>								
Continuing Therapy Only:								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
2234N NP	mesalazine 1 g granules: modified release, 120 x 1 g sachets	1	5	..	331.01	37.70	Pentasa	FP
3413P NP	mesalazine 1 g tablet: modified release, 60 tablets	2	5	..	*331.02	37.70	Pentasa	FP
2287J NP	mesalazine 2 g granules: modified release, 60 x 2 g sachets	1	5	..	312.64	37.70	Pentasa	FP
1611T NP	mesalazine 250 mg tablet: enteric, 100 tablets	1	5	..	93.77	37.70	Mesasal	AS
8731M NP	mesalazine 500 mg tablet: enteric, 100 tablets	2	5	..	*297.78	37.70	Salofalk	OA
2214M NP	mesalazine 500 mg tablet: modified release, 100 tablets	2	5	..	*297.78	37.70	Pentasa	FP
MESALAZINE								
<u>Restricted benefit</u>								
Acute episode of mild to moderate ulcerative proctitis								
<u>Note</u>								
Not for the treatment of Crohn disease								
<u>Note</u>								
No increase in the maximum quantity or number of units may be authorised.								
<u>Note</u>								
No increase in the maximum number of repeats may be authorised.								
<u>Note</u>								
Continuing Therapy Only:								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
5461K NP	mesalazine 1 g suppository, 30	1	1	..	136.73	37.70	Salofalk	OA
8752P NP	mesalazine 1 g suppository, 30	1	1	..	136.73	37.70	Pentasa	FP
MESALAZINE								
<u>Authority required (STREAMLINED)</u>								
4888								
Acute episode of mild to moderate ulcerative colitis								
<u>Note</u>								
Not for the treatment of Crohn disease								
<u>Note</u>								
No increase in the maximum quantity or number of units may be authorised.								
<u>Note</u>								
No increase in the maximum number of repeats may be authorised.								
<u>Note</u>								
Continuing Therapy Only:								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8753Q NP	mesalazine 1 g/100 mL enema, 7 x 100 mL	4	1	..	*336.56	37.70	Pentasa	FP
8768L NP	mesalazine 1 g/application enema, 14 applications	4	1	..	*336.56	37.70	Salofalk	OA
8616L NP	mesalazine 2 g/60 mL enema, 7 x 60 mL	4	1	..	*336.56	37.70	Salofalk	OA
8617M	mesalazine 4 g/60 mL enema, 7 x 60 mL	4	1	..	*446.24	37.70	Salofalk	OA

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
NP								
	OLSALAZINE							
	<u>Authority required (STREAMLINED)</u>							
	4824							
	Ulcerative colitis							
	Clinical criteria:							
	Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR							
	Patient must be intolerant to sulfasalazine.							
	<u>Note</u>							
	Not for the treatment of Crohn disease							
	<u>Note</u>							
	Continuing Therapy Only:							
	For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
1728Y NP	olsalazine sodium 250 mg capsule, 100	1	5	..	61.75	37.70	Dipentum	IX
8086N NP	olsalazine sodium 500 mg tablet, 100	1	5	..	103.63	37.70	Dipentum	IX

SULFASALAZINE

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2096H NP	SULFASALAZINE Tablet 500 mg (enteric coated), 100	2	5	..	*54.60	37.70	^a Pyralin EN	FZ
				^B 2.48	*57.08	37.70	^a Salazopyrin-EN	PF
2093E NP	sulfasalazine 500 mg tablet, 100	2	5	..	*50.62	37.70	Salazopyrin	PF

SULFASALAZINE

Restricted benefit

For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

9209Q	SULFASALAZINE Tablet 500 mg (enteric coated), 100	2	11	..	*54.60	37.70	^a Pyralin EN	FZ
				^B 2.48	*57.08	37.70	^a Salazopyrin-EN	PF
9208P	sulfasalazine 500 mg tablet, 100	2	11	..	*50.62	37.70	Salazopyrin	PF

DIGESTIVES, INCL. ENZYMES

DIGESTIVES, INCL. ENZYMES

Enzyme preparations

PANCREATIC EXTRACT

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8020D NP	pancreatic extract 10 000 international units capsule: modified release, 100 capsules	5	10	..	*184.01	37.70	Creon 10,000	GO
8021E NP	pancreatic extract 25 000 international units capsule: modified release, 100 capsules	2	10	..	*148.08	37.70	Creon 25,000	GO
9412J NP	pancreatic extract 40 000 international units capsule: modified release, 100	2	10	..	*230.30	37.70	Creon 40,000	GO

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
5453B NP	capsules pancreatic extract 5000 international units/100 mg granules: enteric-coated, 20 g	3	10	..	*142.12	37.70	Creon Micro	GO
PANCREATIC EXTRACT								
<u>Restricted benefit</u>								
For use in patients with cystic fibrosis, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements								
<u>Note</u>								
No applications for increased maximum quantities and/or repeats will be authorised.								
9226N	pancreatic extract 10 000 international units capsule: modified release, 100 capsules	5	21	..	*184.01	37.70	Creon 10,000	GO
9227P	pancreatic extract 25 000 international units capsule: modified release, 100 capsules	2	21	..	*148.08	37.70	Creon 25,000	GO
9413K	pancreatic extract 40 000 international units capsule: modified release, 100 capsules	2	21	..	*230.30	37.70	Creon 40,000	GO
5454C	pancreatic extract 5000 international units/100 mg granules: enteric-coated, 20 g	3	21	..	*142.12	37.70	Creon Micro	GO
PANCRELIPASE								
<u>Note</u>								
Continuing Therapy Only:								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8366H NP	pancrelipase 25 000 units capsule, 100	2	10	..	*138.24	37.70	Panzytrat 25000	TM
PANCRELIPASE								
<u>Restricted benefit</u>								
For use in patients with cystic fibrosis, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements								
<u>Note</u>								
No applications for increased maximum quantities and/or repeats will be authorised.								
9229R	pancrelipase 25 000 units capsule, 100	2	21	..	*138.24	37.70	Panzytrat 25000	TM

DRUGS USED IN DIABETES

INSULINS AND ANALOGUES

Insulins and analogues for injection, fast-acting

INSULIN ASPART								
8571D NP	insulin aspart 100 international units/mL injection, 1 x 10 mL vial	5	2	..	*159.61	37.70	NovoRapid	NO
8435Y NP	insulin aspart 100 international units/mL injection, 5 x 3 mL cartridges	5	1	..	*264.56	37.70	NovoRapid FlexPen	NF
							NovoRapid Penfill 3 mL	NO
INSULIN GLULISINE								
9224L NP	insulin glulisine 100 international units/mL injection, 1 x 10 mL vial	5	2	..	*159.61	37.70	Apidra	SW
1921D NP	insulin glulisine 100 international units/mL injection, 5 x 3 mL cartridges	5	1	..	*264.56	37.70	Apidra	AV
							Apidra SoloStar	SW
INSULIN LISPRO								
8084L NP	insulin lispro 100 international units/mL injection, 1 x 10 mL vial	5	2	..	*159.61	37.70	Humalog	LY
8212F NP	insulin lispro 100 international units/mL injection, 5 x 3 mL cartridges	5	1	..	*264.56	37.70	Humalog	LY
							Humalog KwikPen	KP

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
INSULIN NEUTRAL BOVINE								
<u>Authority required</u>								
Diabetes mellitus								
Clinical criteria:								
Patient must be intolerant to human insulin.								
1713E NP	insulin neutral bovine 100 international units/mL injection, 1 x 10 mL vial	5	2	..	*401.06	37.70	Hypurin Neutral	AS
INSULIN NEUTRAL HUMAN								
1531N NP	insulin neutral human 100 international units/mL injection, 1 x 10 mL vial	5	2	..	*134.16	37.70	Actrapid	NO
1762R NP	insulin neutral human 100 international units/mL injection, 5 x 3 mL cartridges	5	1	..	*224.66	37.70	Humulin R Actrapid Penfill 3 mL	LY NO
							Humulin R	LY
<i>Insulins and analogues for injection, intermediate-acting</i>								
INSULIN ISOPHANE BOVINE								
<u>Authority required</u>								
Diabetes mellitus								
Clinical criteria:								
Patient must be intolerant to human insulin.								
1711C NP	insulin isophane bovine 100 international units/mL injection, 1 x 10 mL vial	5	2	..	*401.06	37.70	Hypurin Isophane	AS
INSULIN ISOPHANE HUMAN								
1533Q NP	insulin isophane human 100 international units/mL injection, 1 x 10 mL vial	5	2	..	*134.16	37.70	Humulin NPH	LY
1761Q NP	insulin isophane human 100 international units/mL injection, 5 x 3 mL cartridges	5	1	..	*224.66	37.70	Protaphane Humulin NPH	NO LY
							Protaphane InnoLet Protaphane Penfill 3 mL	NI NO
<i>Insulins and analogues for injection, intermediate-acting combined with fast-acting</i>								
INSULIN ASPART + INSULIN ASPART PROTAMINE								
8609D NP	insulin aspart 30 international units/mL + insulin aspart protamine 70 international units/mL injection, 5 x 3 mL syringes	5	1	..	*264.56	37.70	NovoMix 30 FlexPen	NF
							NovoMix 30 Penfill 3 mL	NO
INSULIN ISOPHANE HUMAN + INSULIN NEUTRAL HUMAN								
1763T NP	insulin isophane human 70 international units/mL + insulin neutral human 30 international units/mL injection, 5 x 3 mL cartridges	5	1	..	*224.66	37.70	Humulin 30/70	LY
							Mixtard 30/70 InnoLet Mixtard 30/70 Penfill 3 mL	NI NO
1426C NP	insulin neutral human 30 international units/mL + insulin isophane human 70 international units/mL injection, 1 x 10 mL vial	5	2	..	*134.16	37.70	Humulin 30/70	LY
2062M NP	insulin neutral human 50 international units/mL + insulin isophane human 50 international units/mL injection, 5 x 3 mL cartridges	5	1	..	*224.66	37.70	Mixtard 50/50 Penfill 3 mL	NO
INSULIN LISPRO + INSULIN LISPRO PROTAMINE								
8390N NP	insulin lispro 25 international units/mL + insulin lispro protamine 75	5	1	..	*264.56	37.70	Humalog Mix25	LY

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	international units/mL injection, 5 x 3 mL cartridges							
8874C NP	insulin lispro 50 international units/mL + insulin lispro protamine 50 international units/mL injection, 5 x 3 mL cartridges	5	1	..	*264.56	37.70	Humalog Mix25 KwikPen Humalog Mix50	KP LY
							Humalog Mix50 KwikPen	KP

Insulins and analogues for injection, long-acting

INSULIN DETEMIR

Restricted benefit

Type 1 diabetes

9040T NP	insulin detemir 100 international units/mL injection, 5 x 3 mL cartridges	5	1	..	*433.06	37.70	Levemir FlexPen	NF
							Levemir Penfill	NO

INSULIN GLARGINE

9039R NP	insulin glargine 100 international units/mL injection, 5 x 3 mL cartridges	5	1	..	*433.06	37.70	Lantus	SW
							Lantus SoloStar	AV

BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS

Biguanides

METFORMIN

8607B NP	metformin hydrochloride 1 g tablet, 90	1	5	..	12.77	13.92	^a APO-Metformin 1000	TX
							^a Chem mart Metformin 1000	CH
							^a Diaformin 1000	AF
							^a Formet 1000	QA
							^a Glucobete 1000	DO
							^a Metformin AN	EA
							^a Metformin-GA	GN
							^a Metformin generichealth 1000	GQ
							^a Metformin Ranbaxy 1000	RA
							^a Metformin Sandoz	SZ
							^a Pharmacor Metformin 1000	CR
							^a Terry White Chemists Metformin 1000	TW
				^b 2.51	15.28	13.92	^a Diabex 1000	AL
3439B NP	metformin hydrochloride 1 g tablet: modified release, 60 tablets	1	5	..	12.29	13.44	^a APO-Metformin XR 1000	TX
							^a Diaformin XR 1000	AF
				^b 2.52	14.81	13.44	^a Diabex XR 1000	AL
2430X NP	metformin hydrochloride 500 mg tablet, 100	1	5	..	10.21	11.36	^a APO-Metformin 500	TX
							^a Chem mart Metformin	CH
							^a Diaformin	AF
							^a Formet Aspen 500	AS
							^a Glucobete 500	DO
							^a Metformin 500	CR
							^a Metformin AN	EA
							^a Metformin-GA	GN
							^a Metformin generichealth	GQ
							^a Metformin Ranbaxy	RA
							^a Metformin Sandoz	SZ
							^a Terry White Chemists Metformin	TW
				^b 2.52	12.73	11.36	^a Diabex	AL

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
9435N NP	metformin hydrochloride 500 mg tablet: modified release, 120 tablets	1	5	..	12.29	13.44	^a APO-Metformin XR 500	TX
							^a Chem mart Metformin XR 500	CH
							^a Diaformin XR	AF
							^a Metex XR	QA
							^a Terry White Chemists Metformin XR 500	TW
				^B 2.52	14.81	13.44	^a Diabex XR	AL
1801T NP	metformin hydrochloride 850 mg tablet, 60	1	5	..	10.21	11.36	^a APO-Metformin 850	TX
							^a Chem mart Metformin	CH
							^a Diaformin 850	AF
							^a Formet Aspen 850	AS
							^a Glucobete 850	DO
							^a Metformin 850	CR
							^a Metformin AN	EA
							^a Metformin-GA	GN
							^a Metformin generichealth	GQ
							^a Metformin Ranbaxy	RA
							^a Metformin Sandoz	SZ
							^a Terry White Chemists Metformin	TW
				^B 0.56	10.77	11.36	^a Glucophage	MQ
				^B 2.52	12.73	11.36	^a Diabex 850	AL

Sulfonamides, urea derivatives

GLIBENCLAMIDE

Caution

Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

2939Q NP	glibenclamide 5 mg tablet, 100	1	5	..	11.73	12.88	^a Glimel	AF
				^B 1.44	13.17	12.88	^a Daonil	SW

GLICLAZIDE

Caution

Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

8535F NP	gliclazide 30 mg tablet: modified release, 100 tablets	1	5	..	13.69	14.84	^a APO-Gliclazide MR	TX
							^a Chem mart Gliclazide MR	CH
							^a Glyade MR	AF
							^a Oziclide MR	RA
							^a Terry White Chemists Gliclazide MR	TW
9302N NP	gliclazide 60 mg tablet: modified release, 60 tablets	1	5	..	15.09	16.24	^a ARDIX GLICLAZIDE 60mg MR	RX
				^B 1.94	17.03	16.24	^a Diamicron 60mg MR	SE
2449X NP	gliclazide 80 mg tablet, 100	1	5	..	13.50	14.65	^a Chem mart Gliclazide	CH
							^a GenRx Gliclazide	GX
							^a Glyade	AF
							^a Nidem	QA
							^a Terry White Chemists Gliclazide	TW

GLIMEPIRIDE

Caution

Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

8450R NP	glimepiride 1 mg tablet, 30	1	5	..	8.19	9.34	^a APO-Glimepiride	TX
							^a Aylide 1	AF
							^a Diapride 1	QA
							^a Dimirel	AV
							^a Glimepiride AN	EA

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
8451T NP	glimepiride 2 mg tablet, 30	1	5	^B 2.89 ..	11.08 9.49	9.34 10.64	^a Glimepiride GA 1	GN
							^a Glimepiride Sandoz	SZ
							^a Amaryl	SW
							^a APO-Glimepiride	TX
							^a Aylide 2	AF
							^a Diapride 2	QA
							^a Dimirel	AV
							^a Glimepiride AN	EA
							^a Glimepiride GA 2	GN
							^a Glimepiride Sandoz	SZ
8533D NP	glimepiride 3 mg tablet, 30	1	5	^B 2.82 ..	12.31 10.22	10.64 11.37	^a Amaryl	SW
							^a APO-Glimepiride	TX
							^a Aylide 3	AF
							^a Diapride 3	QA
							^a Dimirel	AV
							^a Glimepiride AN	EA
							^a Glimepiride GA 3	GN
							^a Glimepiride Sandoz	SZ
							^a Amaryl	SW
							^a APO-Glimepiride	TX
8452W NP	glimepiride 4 mg tablet, 30	1	5	^B 2.84 ..	13.06 11.02	11.37 12.17	^a Aylide 4	AF
							^a Diapride 4	QA
							^a Dimirel	AV
							^a Glimepiride AN	EA
							^a Glimepiride GA 4	GN
							^a Glimepiride Sandoz	SZ
							^a Amaryl	SW
							^a Aylide 4	AF
							^a Diapride 4	QA
							^a Dimirel	AV
				^B 2.84	13.86	12.17	^a Aylide 4	AF
							^a Diapride 4	QA
							^a Dimirel	AV
							^a Glimepiride AN	EA
							^a Glimepiride GA 4	GN
							^a Glimepiride Sandoz	SZ
							^a Amaryl	SW
							^a Aylide 4	AF
							^a Diapride 4	QA
							^a Dimirel	AV
2440K NP	glipizide 5 mg tablet, 100	1	5	..	14.60	15.75	^a Melizide	AF
							^a Minidiab	PF
							^a Minidiab	PF

GLIPIZIDE

Caution

Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

Combinations of oral blood glucose lowering drugs

ALOGLIPTIN + METFORMIN

Authority required (STREAMLINED)

4423

Diabetes mellitus type 2

Clinical criteria:

Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

Authority required (STREAMLINED)

4427

Diabetes mellitus type 2

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and alogliptin.

Note

This fixed dose combination tablet is not PBS-subsidised for use in combination with a sulfonylurea (triple oral therapy), as initial therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

10035E NP	alogliptin 12.5 mg + metformin hydrochloride 1 g tablet, 56	1	5	..	62.77	37.70	Nesina Met 12.5/1000	TK
10033C NP	alogliptin 12.5 mg + metformin hydrochloride 500 mg tablet, 56	1	5	..	61.05	37.70	Nesina Met 12.5/500	TK
10032B NP	alogliptin 12.5 mg + metformin hydrochloride 850 mg tablet, 56	1	5	..	62.28	37.70	Nesina Met 12.5/850	TK

LINAGLIPTIN + METFORMIN

Authority required (STREAMLINED)

4423

Diabetes mellitus type 2

Clinical criteria:

Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

Authority required (STREAMLINED)

4448

Diabetes mellitus type 2

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and linagliptin.

Note

This fixed dose combination tablet is not PBS-subsidised for use in combination with a sulfonylurea (triple oral therapy), as initial therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
10044P NP	linagliptin 2.5 mg + metformin hydrochloride 1 g tablet, 60	1	5	..	66.79	37.70	Trajentamet	BY
10038H NP	linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60	1	5	..	64.93	37.70	Trajentamet	BY
10045Q NP	linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60	1	5	..	66.25	37.70	Trajentamet	BY

METFORMIN + GLIBENCLAMIDE

Caution

Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

8838E NP	metformin hydrochloride 250 mg + glibenclamide 1.25 mg tablet, 90	1	5	..	14.86	16.01	Glucovance 250mg/1.25mg	AL
8810Q NP	metformin hydrochloride 500 mg + glibenclamide 2.5 mg tablet, 90	1	5	..	15.51	16.66	Glucovance 500mg/2.5mg	AL
8811R NP	metformin hydrochloride 500 mg + glibenclamide 5 mg tablet, 90	1	5	..	17.02	18.17	Glucovance 500mg/5mg	AL

ROSIGLITAZONE + METFORMIN

Authority required

Diabetes mellitus type 2

Clinical criteria:

Patient must have a contraindication to a sulfonylurea; OR

Patient must not have tolerated a sulfonylurea,

AND

Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with metformin; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

Note

This fixed dose combination tablet is not PBS-subsidised for use in combination with a sulfonylurea (triple oral therapy), or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a glucagon-like peptide-1, an insulin or an SGLT2 inhibitor.

9060W NP	rosiglitazone 2 mg + metformin hydrochloride 1 g tablet, 56	1	5	..	65.06	37.70	Avandamet	GK
9059T NP	rosiglitazone 2 mg + metformin hydrochloride 500 mg tablet, 56	1	5	..	63.33	37.70	Avandamet	GK
9062Y NP	rosiglitazone 4 mg + metformin hydrochloride 1 g tablet, 56	1	5	..	94.52	37.70	Avandamet	GK
9061X NP	rosiglitazone 4 mg + metformin hydrochloride 500 mg tablet, 56	1	5	..	92.79	37.70	Avandamet	GK

SAXAGLIPTIN + METFORMIN

Authority required (STREAMLINED)

4423

Diabetes mellitus type 2

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

Clinical criteria:

Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

Authority required (STREAMLINED)

4451

Diabetes mellitus type 2

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and saxagliptin.

Note

This fixed dose combination tablet is not PBS-subsidised for use in combination with a sulfonylurea (triple oral therapy), as initial therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

10048W NP	saxagliptin 2.5 mg + metformin hydrochloride 1 g tablet: modified release, 56	1	5	..	62.77	37.70	Kombiglyze XR 2.5/1000	AP
10051B NP	saxagliptin 5 mg + metformin hydrochloride 1 g tablet: modified release, 28	1	5	..	61.05	37.70	Kombiglyze XR 5/1000	AP
10055F NP	saxagliptin 5 mg + metformin hydrochloride 500 mg tablet: modified release, 28	1	5	..	60.12	37.70	Kombiglyze XR 5/500	AP

SITAGLIPTIN + METFORMIN

Authority required (STREAMLINED)

4423

Diabetes mellitus type 2

Clinical criteria:

Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
 (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

Authority required (STREAMLINED)

4309

Diabetes mellitus type 2

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and sitagliptin.

Note

This fixed dose combination tablet is not PBS-subsidised for use in combination with a sulfonylurea (triple oral therapy), as initial therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

10089B NP	sitagliptin 100 mg + metformin hydrochloride 1 g tablet: modified release, 28	1	5	..	61.05	37.70	Janumet XR	MK
9451K NP	sitagliptin 50 mg + metformin hydrochloride 1 g tablet, 56	1	5	..	62.77	37.70	Janumet	MK
10090C NP	sitagliptin 50 mg + metformin hydrochloride 1 g tablet: modified release, 56	1	5	..	62.77	37.70	Janumet XR	MK
9449H NP	sitagliptin 50 mg + metformin hydrochloride 500 mg tablet, 56	1	5	..	61.05	37.70	Janumet	MK
9450J NP	sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56	1	5	..	62.28	37.70	Janumet	MK

VILDAGLIPTIN + METFORMIN

Authority required (STREAMLINED)

4423

Diabetes mellitus type 2

Clinical criteria:

Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
 (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

Authority required (STREAMLINED)

4308

Diabetes mellitus type 2

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and vildagliptin.

Note

This fixed dose combination tablet is not PBS-subsidised for use in combination with a sulfonylurea (triple oral therapy), as initial therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

5476F NP	vildagliptin 50 mg + metformin hydrochloride 1 g tablet, 60	1	5	..	63.71	37.70	Galvumet 50/1000	NV
5474D NP	vildagliptin 50 mg + metformin hydrochloride 500 mg tablet, 60	1	5	..	61.85	37.70	Galvumet 50/500	NV
5475E NP	vildagliptin 50 mg + metformin hydrochloride 850 mg tablet, 60	1	5	..	63.18	37.70	Galvumet 50/850	NV

Alpha glucosidase inhibitors

ACARBOSE

8189B NP	acarbose 100 mg tablet, 90	1	5	..	45.87	37.70	Glucobay 100	BN
8188Y NP	acarbose 50 mg tablet, 90	1	5	..	34.87	36.02	Glucobay 50	BN

Thiazolidinediones

PIOGLITAZONE

Authority required (STREAMLINED)

4363

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea,

AND

Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR

Patient must not have tolerated a combination of metformin and a sulfonylurea,

AND

Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with either metformin or a sulfonylurea; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

Authority required (STREAMLINED)

4388

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with insulin,

AND

Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

Authority required (STREAMLINED)

4364

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin,

AND

The treatment must be in combination with a sulfonylurea,

AND

Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

Note

This drug is not PBS-subsidised for use as monotherapy or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a glucagon-like peptide-1

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	or an SGLT2 inhibitor.						
8694N NP	pioglitazone 15 mg tablet, 28	1	5	..	24.86	26.01	a Acpio 15 QA a Actos TK a APOTEX-Pioglitazone TX a Chem mart Pioglitazone CH a Pharmacor Pioglitazone 15 CR a Pioglitazone AN EA a Pioglitazone-GA GN a Pioglitazone generichealth 15 GQ a Pioglitazone Sandoz SZ a Pizaccord RA a Prioten 15 DO a Terry White Chemists Pioglitazone TW a Vexazone AF
8695P NP	pioglitazone 30 mg tablet, 28	1	5	..	34.60	35.75	a Acpio 30 QA a Actos TK a APOTEX-Pioglitazone TX a Chem mart Pioglitazone CH a Pharmacor Pioglitazone 30 CR a Pioglitazone AN EA a Pioglitazone-GA GN a Pioglitazone generichealth 30 GQ a Pioglitazone Sandoz SZ a Pizaccord RA a Prioten 30 DO a Terry White Chemists Pioglitazone TW a Vexazone AF
8696Q NP	pioglitazone 45 mg tablet, 28	1	5	..	42.74	37.70	a Acpio 45 QA a Actos TK a APOTEX-Pioglitazone TX a Chem mart Pioglitazone CH a Pharmacor Pioglitazone 45 CR a Pioglitazone AN EA a Pioglitazone-GA GN a Pioglitazone generichealth 45 GQ a Pioglitazone Sandoz SZ a Pizaccord RA a Prioten 45 DO a Terry White Chemists Pioglitazone TW a Vexazone AF

ROSIGLITAZONE

Authority required

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea,

AND

Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR

Patient must not have tolerated a combination of metformin and a sulfonylurea,

AND

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with either metformin or a sulfonylurea; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with either metformin or a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.							
8689H	rosiglitazone 4 mg tablet, 28	1	5	..	61.49	37.70	Avandia	GK
NP								
8690J	rosiglitazone 8 mg tablet, 28	1	5	..	90.94	37.70	Avandia	GK
NP								

Note

This drug is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a glucagon-like peptide-1, an insulin or an SGLT2 inhibitor.

Dipeptidyl peptidase 4 (DPP-4) inhibitors

ALOGLIPTIN

Authority required (STREAMLINED)

4349

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea,

AND

Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with alogliptin.

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	

Note

Alogliptin is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

2933J NP	alogliptin 12.5 mg tablet, 28	1	5	..	59.20	37.70	Nesina	TK
2986E NP	alogliptin 25 mg tablet, 28	1	5	..	59.20	37.70	Nesina	TK
2944Y NP	alogliptin 6.25 mg tablet, 28	1	5	..	59.20	37.70	Nesina	TK

LINAGLIPTIN

Authority required (STREAMLINED)

4488

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea,

AND

Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with linagliptin.

Note

Linagliptin is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

3387G NP	linagliptin 5 mg tablet, 30	1	5	..	62.95	37.70	Trajenta	BY

SAXAGLIPTIN

Authority required (STREAMLINED)

4520

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea,

AND

Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with saxagliptin.

Note

Saxagliptin is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

10128C NP	saxagliptin 2.5 mg tablet, 28	1	5	..	59.20	37.70	Onglyza	AP
8983T NP	saxagliptin 5 mg tablet, 28	1	5	..	59.20	37.70	Onglyza	AP

SITAGLIPTIN

Authority required (STREAMLINED)

4519

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea,

AND

Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with sitagliptin.

Note

Sitagliptin is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

9182G NP	sitagliptin 100 mg tablet, 28	1	5	..	59.20	37.70	Januvia	MK
9180E NP	sitagliptin 25 mg tablet, 28	1	5	..	59.20	37.70	Januvia	MK
9181F NP	sitagliptin 50 mg tablet, 28	1	5	..	59.20	37.70	Januvia	MK

VILDAGLIPTIN

Authority required (STREAMLINED)

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	4467 Diabetes mellitus type 2 Clinical criteria: The treatment must be in combination with metformin; OR The treatment must be in combination with a sulfonylurea, AND Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with vildagliptin. Note Vildagliptin is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.						
3415R NP	vildagliptin 50 mg tablet, 60	1	5	..	62.95	37.70	Galvus NV

Other blood glucose lowering drugs, excl. insulins

CANAGLIFLOZIN

Authority required

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea,

AND

The condition must not be able to be adequately controlled by treatment with metformin and a sulfonylurea,

AND

Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co- transporter 2 (SGLT2) inhibitor; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.								
Note								
Continuing Therapy Only:								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
Note								
This drug is not PBS subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with an insulin, a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.								
2873F NP	canagliflozin 100 mg tablet, 30	1	5	..	96.61	37.70	Invokana	JC
2987F NP	canagliflozin 300 mg tablet, 30	1	5	..	96.61	37.70	Invokana	JC

DAPAGLIFLOZIN

Authority required (STREAMLINED)

4844

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea,

AND

Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

Authority required (STREAMLINED)

4825

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with insulin,

AND

Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note

Dapagliflozin is not PBS subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

10011X NP	dapagliflozin 10 mg tablet, 28	1	5	..	58.66	37.70	Forxiga	AP

EMPAGLIFLOZIN

Authority required (STREAMLINED)

4848

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea,

AND

Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
This drug is not PBS subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with an insulin, a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.								
10206E NP	empagliflozin 10 mg tablet, 30	1	5	..	62.37	37.70	Jardiance	BY
10202Y NP	empagliflozin 25 mg tablet, 30	1	5	..	62.37	37.70	Jardiance	BY

EXENATIDE

Authority required (STREAMLINED)

4856

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea,

AND

Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR

Patient must not have tolerated a combination of metformin and a sulfonylurea,

AND

Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with either metformin or a sulfonylurea; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

Authority required (STREAMLINED)

4857

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin,

AND

The treatment must be in combination with a sulfonylurea,

AND

Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.							
	Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:							
	(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or							
	(b) Had red cell transfusion within the previous 3 months.							
	The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.							
	Note							
	This drug is not PBS-subsidised for use as monotherapy or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), an insulin or an SGLT2 inhibitor.							
3424F NP	exenatide 10 microgram/0.04 mL injection, 60 unit doses	1	5	..	97.60	37.70	Byetta 10 microgram	AP
3423E NP	exenatide 5 microgram/0.02 mL injection, 60 unit doses	1	5	..	70.34	37.70	Byetta 5 microgram	AP

VITAMINS

VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO *Vitamin D and analogues*

CALCITRIOL

Authority required (STREAMLINED)

1165

Hypocalcaemia due to renal disease

Authority required (STREAMLINED)

1166

Hypoparathyroidism

Authority required (STREAMLINED)

1167

Hypophosphataemic rickets

Authority required (STREAMLINED)

1467

Vitamin D-resistant rickets

Authority required (STREAMLINED)

2636

Treatment for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body

2502Q NP	calcitriol 0.25 microgram capsule, 100	1	3	..	30.62	31.77	^a Calciprox	ER
							^a Calcitriol AN	EA
							^a Calcitriol-GA	UA
							^a Calcitriol Sandoz	SZ
							^a GenRx Calcitriol	GX
							^a Kosteol	QA
							^a Rocaltrol	RO
							^a Sical	AF

VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12 *Vitamin B1, plain*

THIAMINE

Authority required (STREAMLINED)

2384

Prophylaxis of thiamine deficiency in an Aboriginal or a Torres Strait Islander person

1070H NP	thiamine hydrochloride 100 mg tablet, 100	1	2	..	10.45	11.60	Betavit	PP

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

MINERAL SUPPLEMENTS

CALCIUM

Calcium

CALCIUM

Authority required (STREAMLINED)

4586

Hyperphosphataemia

Clinical criteria:

The condition must be associated with chronic renal failure.

3116B NP	CALCIUM Tablet (chewable) 500 mg (as carbonate), 60	4	1	..	*29.24	30.39	^a Cal-500	PP
							^a Cal-Sup	IA
3117C NP	CALCIUM Tablet 600 mg (as carbonate), 240	1	1	..	22.54	23.69	Calci-Tab 600	AE

POTASSIUM

Potassium

POTASSIUM CHLORIDE

Note

For item codes 2642C and 1841X, pharmaceutical benefits that have the form tablet 600 mg (sustained release) are equivalent for the purposes of substitution.

2642C NP	potassium chloride 600 mg (8 mmol potassium) tablet: modified release, 100 tablets	2	1	..	*13.22	14.37	^a Duro-K	NM
				^b 2.94	*16.16	14.37	^a Slow-K	NV
1841X NP	potassium chloride 600 mg (8 mmol potassium) tablet: modified release, 200 tablets	1	1	..	13.21	14.36	^a Span-K	AS

POTASSIUM CHLORIDE + POTASSIUM BICARBONATE + POTASSIUM CARBONATE

3012M NP	potassium chloride 595 mg + potassium bicarbonate 384 mg + potassium carbonate 152 mg (total potassium 14 mmol) tablet: effervescent, 60	1	1	..	15.48	16.63	Chlorvescent	AS

OTHER MINERAL SUPPLEMENTS

Magnesium

MAGNESIUM ASPARTATE DIHYDRATE

Authority required

Hypomagnesaemia in an Aboriginal or a Torres Strait Islander person

Authority required

Chronic renal disease in an Aboriginal or a Torres Strait Islander person

5146W NP	magnesium aspartate dihydrate 500 mg (equivalent to 37.4 mg of magnesium) tablet, 50	1	5	..	14.04	15.19	MagMin (PBS)	BB
							Mag-Sup	PP

ANABOLIC AGENTS FOR SYSTEMIC USE

ANABOLIC STEROIDS

Estren derivatives

NANDROLONE DECANOATE

Authority required

Monotherapy for osteoporosis, where other treatment has failed and where specialist advice confirms that this is the only suitable treatment option for the patient. Specialist advice need only be obtained for the first authority approval

Authority required

Monotherapy for osteoporosis, where other treatment is not tolerated and where specialist advice confirms that this is the only suitable treatment option for the patient. Specialist advice need only be obtained for the first authority approval

Authority required

Monotherapy for osteoporosis, where other treatment is contraindicated and where specialist advice confirms that this is the only suitable

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	treatment option for the patient. Specialist advice need only be obtained for the first authority approval							
	<u>Authority required</u>							
	Patients receiving PBS-subsidised therapy with this drug for osteoporosis prior to 1 February 2004							
	<u>Authority required</u>							
	Patients on long-term treatment with corticosteroids							
	<u>Note</u>							
	Monotherapy for the treatment of osteoporosis does not exclude calcium supplementation.							
1671Y	nandrolone decanoate 50 mg/mL injection, 1 x 1 mL syringe	1	7	..	21.54	22.69	Deca-Durabolin	AS

OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS

OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS

Amino acids and derivatives

BETAINE

Authority required

Homocystinuria

Clinical criteria:

The treatment must be as adjunctive therapy to current standard care,

AND

The condition must be treated by or in consultation with a metabolic physician.

The name of the specialist must be included in the authority application.

10119N	betaine 1 g/g oral liquid: powder for, 180 g	\$1	5	..	570.55	37.70	Cystadane	EU

Various alimentary tract and metabolism products

SAPROPTERIN

Authority required

Hyperphenylalaninaemia

Treatment Phase: Initial

Clinical criteria:

Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency.

Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured.

The authority application must be made in writing.

Note

Patients will be eligible for a maximum of one script as initial therapy to enable their response to treatment with sapropterin to be assessed.

If a 30% or greater reduction in blood phenylalanine levels is not achieved within one month, the patient is no longer eligible for PBS-subsidised treatment with sapropterin.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

10086W	sapropterin dihydrochloride 100 mg tablet: soluble, 30 tablets	6	..	..	*5306.74	37.70	Kuvan	SG

SAPROPTERIN

Authority required

Hyperphenylalaninaemia

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Treatment Phase: Continuing							
	Clinical criteria:							
	Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency,							
	AND							
	Patient must have previously been issued with an authority prescription for this drug; OR							
	Patient must have accessed non-PBS-subsidised treatment prior to 1 May 2014.							
	Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured.							
	The authority application must be made in writing.							
	Note							
	Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).							
	Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au							
	Applications for authority to prescribe should be forwarded to:							
	Department of Human Services							
	Prior Written Approval of Complex Drugs							
	Reply Paid 9826							
	GPO Box 9826							
	HOBART TAS 7001							
10087X	sapropterin dihydrochloride 100 mg tablet: soluble, 30 tablets	6	5	..	*5306.74	37.70	Kuvan	SG

BLOOD AND BLOOD FORMING ORGANS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

BLOOD AND BLOOD FORMING ORGANS

ANTITHROMBOTIC AGENTS

ANTITHROMBOTIC AGENTS

Vitamin K antagonists

WARFARIN

Caution

The listed brands have NOT been shown to be bioequivalent and should not be interchanged.

2843P NP	warfarin sodium 1 mg tablet, 50	1	2	..	12.75	13.90	Coumadin	QA
2209G NP	warfarin sodium 2 mg tablet, 50	1	2	..	13.11	14.26	Marevan Coumadin	FM QA
2844Q NP	warfarin sodium 3 mg tablet, 50	1	2	..	13.03	14.18	Marevan	FM
2211J NP	warfarin sodium 5 mg tablet, 50	1	2	..	14.37	15.52	Coumadin	QA
							Marevan	FM

Heparin group

DALTEPARIN SODIUM

Restricted benefit

Management of symptomatic venous thromboembolism in a patient with a solid tumour(s)

Note

No applications for increased maximum quantities will be authorised.

8959M NP	DALTEPARIN SODIUM (Low Molecular Weight Heparin Sodium-porcine mucous) Injection 15,000 units (anti-Xa) in 0.6 mL single dose pre-filled syringe, 10	3	5	..	*415.09	37.70	Fragmin	PF
8960N NP	DALTEPARIN SODIUM (Low Molecular Weight Heparin Sodium-porcine mucous) Injection 18,000 units (anti-Xa) in 0.72 mL single dose pre-filled syringe, 10	3	5	..	*493.93	37.70	Fragmin	PF
8957K NP	dalteparin sodium 10 000 anti-Xa international units/mL injection, 10 x 1 mL syringes	3	5	..	*255.40	37.70	Fragmin	PF
8958L NP	dalteparin sodium 12 500 anti-Xa international units/0.5 mL injection, 10 x 0.5 mL syringes	3	5	..	*350.05	37.70	Fragmin	PF
8956J NP	dalteparin sodium 7500 anti-Xa international units/0.75 mL injection, 10 x 0.75 mL syringes	3	5	..	*192.64	37.70	Fragmin	PF

DALTEPARIN SODIUM

Restricted benefit

Haemodialysis

1229Q NP	dalteparin sodium 10 000 anti-Xa international units/mL injection, 10 x 1 mL syringes	2	3	..	*175.90	37.70	Fragmin	PF
1296F NP	dalteparin sodium 12 500 anti-Xa international units/0.5 mL injection, 10 x 0.5 mL syringes	2	3	..	*241.62	37.70	Fragmin	PF
8641T NP	dalteparin sodium 2500 anti-Xa international units/0.2 mL injection, 10 x 0.2 mL syringes	2	3	..	*105.08	37.70	Fragmin	PF
8642W NP	dalteparin sodium 5000 anti-Xa international units/0.2 mL injection, 10 x 0.2 mL syringes	2	3	..	*109.22	37.70	Fragmin	PF
8643X NP	dalteparin sodium 7500 anti-Xa international units/0.75 mL injection, 10 x 0.75 mL syringes	2	3	..	*130.68	37.70	Fragmin	PF

BLOOD AND BLOOD FORMING ORGANS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
DALTEPARIN SODIUM								
8269F NP	dalteparin sodium 10 000 anti-Xa international units/mL injection, 10 x 1 mL syringes	1	1	..	91.33	37.70	Fragmin	PF
5445N NP	dalteparin sodium 12 500 anti-Xa international units/0.5 mL injection, 10 x 0.5 mL syringes	1	1	..	126.03	37.70	Fragmin	PF
8603T NP	dalteparin sodium 2500 anti-Xa international units/0.2 mL injection, 10 x 0.2 mL syringes	2	..	..	*105.08	37.70	Fragmin	PF
2816F NP	dalteparin sodium 5000 anti-Xa international units/0.2 mL injection, 10 x 0.2 mL syringes	2	..	..	*109.22	37.70	Fragmin	PF
8271H NP	dalteparin sodium 7500 anti-Xa international units/0.75 mL injection, 10 x 0.75 mL syringes	1	1	..	68.72	37.70	Fragmin	PF
ENOXAPARIN SODIUM								
<u>Restricted benefit</u>								
Haemodialysis								
5435C NP	enoxaparin sodium 100 mg/mL injection, 10 x 1 mL syringes	2	3	..	*211.42	37.70	Clexane	SW
8716R NP	enoxaparin sodium 20 mg/0.2 mL injection, 10 x 0.2 mL syringes	2	3	..	*105.08	37.70	Clexane	SW
9196B NP	enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL ampoules	2	3	..	*109.22	37.70	Clexane	SW
8639Q NP	enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL syringes	2	3	..	*109.22	37.70	Clexane	SW
8640R NP	enoxaparin sodium 60 mg/0.6 mL injection, 10 x 0.6 mL syringes	2	3	..	*153.28	37.70	Clexane	SW
5434B NP	enoxaparin sodium 80 mg/0.8 mL injection, 10 x 0.8 mL syringes	2	3	..	*175.32	37.70	Clexane	SW
ENOXAPARIN SODIUM								
8264Y NP	enoxaparin sodium 100 mg/mL injection, 10 x 1 mL syringes	1	1	..	109.42	37.70	Clexane	SW
8558K NP	enoxaparin sodium 20 mg/0.2 mL injection, 10 x 0.2 mL syringes	2	..	..	*105.08	37.70	Clexane	SW
9195Y NP	enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL ampoules	2	..	..	*109.22	37.70	Clexane	SW
8510X NP	enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL syringes	2	..	..	*109.22	37.70	Clexane	SW
8262W NP	enoxaparin sodium 60 mg/0.6 mL injection, 10 x 0.6 mL syringes	1	1	..	80.02	37.70	Clexane	SW
8263X NP	enoxaparin sodium 80 mg/0.8 mL injection, 10 x 0.8 mL syringes	1	1	..	91.04	37.70	Clexane	SW
HEPARIN SODIUM								
1076P NP	heparin sodium 35 000 international units/35 mL injection, 1 x 35 mL vial	12	5	..	*380.56	37.70	Hospira Pty Limited	HH
1466E NP	heparin sodium 5000 international units/0.2 mL injection, 5 x 0.2 mL ampoules	1	5	..	19.44	20.59	Hospira Pty Limited	HH
1463B NP	heparin sodium 5000 international units/5 mL injection, 50 x 5 mL ampoules	1	5	..	71.86	37.70	Pfizer Australia Pty Ltd	PF

Platelet aggregation inhibitors excl. heparin

ABCIXIMAB

Authority required (STREAMLINED)

1716

Patients undergoing percutaneous coronary balloon angioplasty

Authority required (STREAMLINED)

1717

Patients undergoing percutaneous coronary atherectomy

Authority required (STREAMLINED)

1718

BLOOD AND BLOOD FORMING ORGANS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
8048N	Patients undergoing percutaneous coronary stent placement abciximab 10 mg/5 mL injection, 1 x 5 mL vial	3	..	..	*1453.45	37.70	ReoPro	LY
8202Q NP	ASPIRIN aspirin 100 mg tablet, 112	1	1	..	8.21	9.36	^a Mayne Pharma Aspirin	YT
1010E NP	aspirin 300 mg tablet: effervescent, 96	1	1	^b 2.32	10.53	9.36	^a Spren 100	QA
				..	8.51	9.66	^a Astrix	YN
							Solprin	RC
CLOPIDOGREL								
<u>Authority required (STREAMLINED)</u>								
4166								
Acute coronary syndrome (myocardial infarction or unstable angina)								
Clinical criteria:								
The treatment must be in combination with aspirin.								
<u>Authority required (STREAMLINED)</u>								
4165								
Cardiac stent insertion								
Clinical criteria:								
The treatment must be in combination with aspirin,								
AND								
The treatment must follow insertion of a cardiac stent.								
<u>Note</u>								
Not for prophylaxis of deep vein thrombosis or peripheral arterial disease.								
<u>Note</u>								
Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution.								
<u>Note</u>								
Shared Care Model:								
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
2275R NP	clopidogrel 75 mg tablet, 28	1	5	..	15.70	16.85	^a Clopidogrel-GA	GN
							^a Clovix 75	QA
							^a Plidogrel	FM
9317J NP	clopidogrel 75 mg tablet, 28	1	5	..	15.70	16.85	^a APO-Clopidogrel	TX
							^a Clopidogrel AN	EA
							^a Clopidogrel Winthrop	WA
							^a Iscover	AV
							^a Piax	AF
							^a Plavix	SW

CLOPIDOGREL

Authority required (STREAMLINED)

1723

Prevention of recurrence of myocardial infarction or unstable angina in patients where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding

Authority required (STREAMLINED)

1724

Prevention of recurrence of myocardial infarction or unstable angina in patients where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs

Authority required (STREAMLINED)

1719

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients with a history of symptomatic cerebrovascular ischaemic episodes while on therapy with low-dose aspirin

Authority required (STREAMLINED)

1720

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients where low-dose aspirin poses an unacceptable risk of

BLOOD AND BLOOD FORMING ORGANS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	gastrointestinal bleeding						
	<u>Authority required (STREAMLINED)</u>						
	1721						
	Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs						
	<u>Authority required (STREAMLINED)</u>						
	1722						
	Prevention of recurrence of myocardial infarction or unstable angina in patients with a history of symptomatic cardiac ischaemic events while on therapy with low-dose aspirin						
	<u>Note</u>						
	Not for prophylaxis of DVT or peripheral arterial disease.						
	<u>Note</u>						
	Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg, clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution.						
	<u>Note</u>						
	Shared Care Model:						
	For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.						
5436D NP	clopidogrel 75 mg tablet, 28	1	5	..	15.70	16.85	^a Clopidogrel-DRLA RZ
8358X NP	clopidogrel 75 mg tablet, 28	1	5	..	15.70	16.85	^a APO-Clopidogrel TX
							^a Chem mart Clopidogrel CH
							^a Clopidogrel AN EA
							^a Clopidogrel RBX RA
							^a Clopidogrel Sandoz SZ
							^a Clopidogrel Winthrop WA
							^a Iscover AV
							^a Piax AF
							^a Plavacor 75 CR
							^a Plavix SW
							^a Terry White Chemists Clopidogrel TW

CLOPIDOGREL

Authority required (STREAMLINED)

1719

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients with a history of symptomatic cerebrovascular ischaemic episodes while on therapy with low-dose aspirin

Authority required (STREAMLINED)

1720

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding

Authority required (STREAMLINED)

1721

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs

Authority required (STREAMLINED)

1722

Prevention of recurrence of myocardial infarction or unstable angina in patients with a history of symptomatic cardiac ischaemic events while on therapy with low-dose aspirin

Authority required (STREAMLINED)

1723

Prevention of recurrence of myocardial infarction or unstable angina in patients where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding

Authority required (STREAMLINED)

1724

Prevention of recurrence of myocardial infarction or unstable angina in patients where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs

Note

Not for prophylaxis of DVT or peripheral arterial disease.

Note

BLOOD AND BLOOD FORMING ORGANS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg, clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution.							
	Note Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
9354H NP	clopidogrel 75 mg tablet, 28	1	5	..	15.70	16.85	^a Clopidogrel Actavis	UA
							^a Clopidogrel-GA	GN
							^a Clopidogrel GH	GQ
							^a Clovix 75	QA
							^a Plidogrel	FM
	CLOPIDOGREL + ASPIRIN Authority required (STREAMLINED) 3880 Treatment of acute coronary syndrome (myocardial infarction or unstable angina) Authority required (STREAMLINED) 3219 Treatment following cardiac stent insertion Authority required (STREAMLINED) 1722 Prevention of recurrence of myocardial infarction or unstable angina in patients with a history of symptomatic cardiac ischaemic events while on therapy with low-dose aspirin							
	Note Not for prophylaxis of DVT or peripheral arterial disease.							
	Note Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
9296G NP	clopidogrel 75 mg + aspirin 100 mg tablet, 30	1	5	..	40.56	37.70	^a APO- Clopidogrel/Aspirin 75/100	TX
							^a Chem mart Clopidogrel/Aspirin 75/100	CH
							^a Clopidogrel/Aspirin Actavis 75/100	GN
							^a Clopidogrel Winthrop plus aspirin	WA
							^a CoPlavix	SW
							^a DuoCover	AV
							^a DuoPlidogrel	GZ
							^a Piax Plus Aspirin	AF
							^a Terry White Chemists Clopidogrel/Aspirin 75/100	TW
	DIPYRIDAMOLE Restricted benefit Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events as adjunctive therapy with low-dose aspirin Restricted benefit Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding Restricted benefit Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs							
	Note Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
8335Q NP	dipyridamole 200 mg capsule: modified release, 60 capsules	1	5	..	37.30	37.70	Persantin SR	BY

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
DIPYRIDAMOLE + ASPIRIN								
<u>Restricted benefit</u>								
Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events								
<u>Note</u>								
Shared Care Model:								
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8382E NP	dipyridamole 200 mg + aspirin 25 mg capsule: modified release, 60 capsules	1	5	..	32.61	33.76 ^a	APO-Dipyridamole/Aspirin 200/25 ^a Asasantin SR	TX BY
EPTIFIBATIDE								
<u>Authority required (STREAMLINED)</u>								
1884								
Patients undergoing non-urgent percutaneous intervention with intracoronary stenting								
8683B	eptifibatide 20 mg/10 mL injection, 1 x 10 mL vial	2	..	..	*262.88	37.70	Integrilin	MK
8684C	eptifibatide 75 mg/100 mL injection, 1 x 100 mL vial	3	..	..	*1020.70	37.70	Integrilin	MK
PRASUGREL								
<u>Authority required (STREAMLINED)</u>								
3208								
Treatment of acute coronary syndrome (myocardial infarction or unstable angina) managed by percutaneous coronary intervention in combination with aspirin								
<u>Note</u>								
Shared Care Model:								
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
9496T NP	prasugrel 10 mg tablet, 28	1	5	..	106.77	37.70	Effient	LY
9495R NP	prasugrel 5 mg tablet, 28	1	5	..	96.77	37.70	Effient	LY
TICAGRELOR								
<u>Authority required (STREAMLINED)</u>								
3879								
Treatment of acute coronary syndrome (myocardial infarction or unstable angina) in combination with aspirin								
<u>Note</u>								
Shared Care Model:								
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
1418P NP	TICAGRELOR Tablet 90 mg, 56	1	5	..	149.34	37.70	Brilinta	AP
TIROFIBAN								
<u>Authority required (STREAMLINED)</u>								
1729								
Patients with high risk unstable angina who have new transient or persistent ST-T ischaemic changes and anginal pain lasting longer than 20 minutes								
<u>Authority required (STREAMLINED)</u>								
1730								
Patients with high risk unstable angina who have new transient or persistent ST-T ischaemic changes and repetitive episodes of angina at rest or during minimal exercise in the previous 12 hours								
<u>Authority required (STREAMLINED)</u>								
1275								
Patients with non-Q-wave myocardial infarction								
<u>Note</u>								
Shared Care Model:								
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								

BLOOD AND BLOOD FORMING ORGANS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
8350L NP	tirofiban 12.5 mg/50 mL injection, 1 x 50 mL vial	1	2	..	309.26	37.70	^a Aggrastat	AS
							^a Tirofiban AC	GN

Enzymes

RETEPLASE

Restricted benefit

Treatment of acute myocardial infarction within 6 hours of onset of attack

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8253J NP	reteplase 10 units (17.4 mg) injection [2 x 10 units vials] (&) inert substance diluent [2 x 10 mL syringes], 1 pack	1	..	..	2067.30	37.70	Rapilysin 10 U	GN

TENECTEPLASE

Restricted benefit

Treatment of acute myocardial infarction within 12 hours of onset of attack

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8527T NP	tenecteplase 10 000 international units (50 mg) injection [1 x 50 mg vial] (&) inert substance diluent [1 x 10 mL syringe], 1 pack	1	..	..	2057.40	37.70	Metalyse	BY
8526R NP	tenecteplase 8000 international units (40 mg) injection [1 x 40 mg vial] (&) inert substance diluent [1 x 8 mL syringe], 1 pack	1	..	..	1961.10	37.70	Metalyse	BY

Direct thrombin inhibitors

BIVALIRUDIN

Authority required (STREAMLINED)

3075

A patient undergoing percutaneous coronary intervention

8844L	bivalirudin 250 mg injection, 1 x 250 mg vial	1	..	..	672.09	37.70	Angiomax	XM

DABIGATRAN

Authority required (STREAMLINED)

4269

Prevention of stroke or systemic embolism

Clinical criteria:

Patient must have non-valvular atrial fibrillation,

AND

Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

- (i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
- (ii) age 75 years or older;
- (iii) hypertension;
- (iv) diabetes mellitus;
- (v) heart failure and/or left ventricular ejection fraction 35% or less.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note

No increase in the maximum quantity or number of units may be authorised.

[illegible]

BLOOD AND BLOOD FORMING ORGANS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Note No increase in the maximum quantity or number of units may be authorised.							
	Note No increase in the maximum number of repeats may be authorised.							
	Note Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
9323Q NP	dabigatran etexilate 110 mg capsule, 10	2	..	..	*37.94	37.70	Pradaxa	BY
9322P NP	dabigatran etexilate 75 mg capsule, 10	2	..	..	*45.88	37.70	Pradaxa	BY

Direct factor Xa inhibitors

APIXABAN

Authority required (STREAMLINED)

4381

Prevention of venous thromboembolism

Clinical criteria:

Patient must require up to 10 days of therapy.

Treatment criteria:

Patient must be undergoing total knee replacement.

Authority required (STREAMLINED)

4359

Prevention of venous thromboembolism

Clinical criteria:

Patient must require up to 10 days supply to complete a course of treatment.

Treatment criteria:

Patient must be undergoing total hip replacement.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

5500L NP	apixaban 2.5 mg tablet, 20	1	..	..	39.79	37.70	Eliquis	BQ

APIXABAN

Authority required (STREAMLINED)

4382

Prevention of venous thromboembolism

Clinical criteria:

Patient must require up to 15 days of therapy.

Treatment criteria:

Patient must be undergoing total knee replacement.

Authority required (STREAMLINED)

4409

Prevention of venous thromboembolism

Clinical criteria:

Patient must require up to 15 days supply to complete a course of treatment.

Treatment criteria:

Patient must be undergoing total hip replacement.

Note

No increase in the maximum quantity or number of units may be authorised.

RIVAROXABAN

BLOOD AND BLOOD FORMING ORGANS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
<u>Authority required (STREAMLINED)</u>								
4402								
Prevention of venous thromboembolism								
Clinical criteria:								
Patient must require up to 30 days supply to complete a course of treatment.								
Treatment criteria:								
Patient must be undergoing total hip replacement.								
Note								
No increase in the maximum quantity or number of units may be authorised.								
Note								
No increase in the maximum number of repeats may be authorised.								
Note								
Shared Care Model:								
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
9467G	RIVAROXABAN Tablet 10 mg, 30	1	..	..	101.14	37.70	Xarelto	BN
NP								
9466F	rivaroxaban 10 mg tablet, 15	1	1	..	54.16	37.70	Xarelto	BN
NP								
RIVAROXABAN								
<u>Authority required (STREAMLINED)</u>								
4369								
Prevention of venous thromboembolism								
Clinical criteria:								
Patient must require up to 20 days supply to complete a course of treatment.								
Treatment criteria:								
Patient must be undergoing total hip replacement.								
Note								
No increase in the maximum quantity or number of units may be authorised.								
Note								
No increase in the maximum number of repeats may be authorised.								
Note								
Shared Care Model:								
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
9465E	rivaroxaban 10 mg tablet, 10	1	1	..	39.65	37.70	Xarelto	BN
NP								
RIVAROXABAN								
<u>Authority required (STREAMLINED)</u>								
4381								
Prevention of venous thromboembolism								
Clinical criteria:								
Patient must require up to 10 days of therapy.								
Treatment criteria:								
Patient must be undergoing total knee replacement.								
Note								
No increase in the maximum quantity or number of units may be authorised.								
Note								
No increase in the maximum number of repeats may be authorised.								
Note								
Shared Care Model:								
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
9468H	rivaroxaban 10 mg tablet, 10	1	..	..	39.65	37.70	Xarelto	BN
NP								

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	RIVAROXABAN						
	<u>Authority required (STREAMLINED)</u>						
	4382						
	Prevention of venous thromboembolism						
	Clinical criteria:						
	Patient must require up to 15 days of therapy.						
	Treatment criteria:						
	Patient must be undergoing total knee replacement.						
	Note						
	No increase in the maximum quantity or number of units may be authorised.						
	Note						
	No increase in the maximum number of repeats may be authorised.						
	Note						
	Shared Care Model:						
	For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.						
9469J NP	rivaroxaban 10 mg tablet, 15	1	..	..	54.16	37.70	Xarelto BN
	RIVAROXABAN						
	<u>Authority required (STREAMLINED)</u>						
	4269						
	Prevention of stroke or systemic embolism						
	Clinical criteria:						
	Patient must have non-valvular atrial fibrillation,						
	AND						
	Patient must have one or more risk factors for developing stroke or systemic embolism.						
	Risk factors for developing stroke or systemic ischaemic embolism are:						
	(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;						
	(ii) age 75 years or older;						
	(iii) hypertension;						
	(iv) diabetes mellitus;						
	(v) heart failure and/or left ventricular ejection fraction 35% or less.						
	Note						
	Shared Care Model:						
	For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.						
	Note						
	No increase in the maximum quantity or number of units may be authorised.						
	Note						
	No increase in the maximum number of repeats may be authorised.						
	Note						
	Special Pricing Arrangements apply.						
2691P NP	rivaroxaban 15 mg tablet, 28	1	5	..	94.85	37.70	Xarelto BN
	RIVAROXABAN						
	<u>Authority required (STREAMLINED)</u>						
	4098						
	Deep vein thrombosis						
	Treatment Phase: Initial treatment						
	Clinical criteria:						
	Patient must have confirmed acute symptomatic deep vein thrombosis,						
	AND						
	Patient must not have symptomatic pulmonary embolism.						
	Note						

2160Q NP	rivaroxaban 15 mg tablet, 42	1	..	..	138.89	37.70	Xarelto	BN

BLOOD AND BLOOD FORMING ORGANS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	No increase in the maximum number of repeats may be authorised.						
	<u>Authority required (STREAMLINED)</u>						
	4268						
	Pulmonary embolism						
	Treatment Phase: Continuing treatment						
	Clinical criteria:						
	Patient must have confirmed acute symptomatic pulmonary embolism.						
	<u>Note</u>						
	Shared Care Model:						
	For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.						
	<u>Note</u>						
	No increase in the maximum quantity or number of units may be authorised.						
	<u>Note</u>						
	No increase in the maximum number of repeats may be authorised.						
	<u>Note</u>						
	Special Pricing Arrangements apply.						
	<u>Authority required (STREAMLINED)</u>						
	4269						
	Prevention of stroke or systemic embolism						
	Clinical criteria:						
	Patient must have non-valvular atrial fibrillation,						
	AND						
	Patient must have one or more risk factors for developing stroke or systemic embolism.						
	Risk factors for developing stroke or systemic ischaemic embolism are:						
	(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;						
	(ii) age 75 years or older;						
	(iii) hypertension;						
	(iv) diabetes mellitus;						
	(v) heart failure and/or left ventricular ejection fraction 35% or less.						
	<u>Note</u>						
	Shared Care Model:						
	For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.						
	<u>Note</u>						
	No increase in the maximum quantity or number of units may be authorised.						
	<u>Note</u>						
	No increase in the maximum number of repeats may be authorised.						
	<u>Note</u>						
	Special Pricing Arrangements apply.						
2268J NP	rivaroxaban 20 mg tablet, 28	1	5	..	94.85	37.70	Xarelto BN

Other antithrombotic agents

FONDAPARINUX

Authority required (STREAMLINED)

2005

Prevention of venous thromboembolic events in patients undergoing major hip surgery

Authority required (STREAMLINED)

2006

Prevention of venous thromboembolic events in patients undergoing total knee replacement

Note

No applications for increased maximum quantities and/or repeats will be authorised.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised

BLOOD AND BLOOD FORMING ORGANS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8775W NP	FONDAPARINUX SODIUM Injection 2.5 mg in 0.5 mL single dose pre-filled syringe, 2	3.5	..	..	*140.88	37.70	Arixtra	AS

ANTIHEMORRHAGICS

ANTIFIBRINOLYTICS

Amino acids

TRANEXAMIC ACID

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2180R NP	tranexamic acid 500 mg tablet, 100	1	2	..	52.02	37.70	Cyklokapron	PF

ANTIANEMIC PREPARATIONS

IRON PREPARATIONS

Iron bivalent, oral preparations

FERROUS FUMARATE

8985X NP	ferrous fumarate 200 mg (equivalent to 65.7 mg of elemental iron) tablet, 60	1	1	..	11.96	13.11	Ferro-tab	AE

FERROUS SULFATE

8815Y NP	ferrous sulfate 30 mg/mL (equivalent to 6 mg/mL elemental iron) oral liquid, 250 mL	1	2	..	19.69	20.84	Ferro-Liquid	AE

Iron trivalent, parenteral preparations

IRON

10104T NP	iron (as ferric carboxymaltose) 500 mg/10 mL injection, 1 x 10 mL vial	2	1	..	*317.22	37.70	ferinject	VL

IRON POLYMALTOSE

2593L NP	iron (as polymaltose) 100 mg/2 mL injection, 5 x 2 mL ampoules	1	..	..	31.88	33.03	^a Ferrosig	SI
							^a Ferrum H	AS

IRON POLYMALTOSE

Authority required (STREAMLINED)

4302

Iron deficiency anaemia

Treatment criteria:

Patient must be undergoing chronic haemodialysis.

2805P NP	iron (as polymaltose) 100 mg/2 mL injection, 5 x 2 mL ampoules	1	5	..	31.88	33.03	^a Ferrosig	SI
							^a Ferrum H	AS

IRON SUCROSE

10229J NP	iron (as sucrose) 100 mg/5 mL injection, 5 x 5 mL ampoules	1	..	..	31.88	33.03	Venofer	AS

IRON SUCROSE

Authority required (STREAMLINED)

4302

Iron deficiency anaemia

Treatment criteria:

Patient must be undergoing chronic haemodialysis.

8807M NP	iron (as sucrose) 100 mg/5 mL injection, 5 x 5 mL ampoules	1	5	..	31.88	33.03	Venofer	AS

Iron in combination with folic acid

BLOOD AND BLOOD FORMING ORGANS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	

9011G NP	FERROUS FUMARATE + FOLIC ACID ferrous fumarate 310 mg (equivalent to 100 mg elemental iron) + folic acid 350 microgram tablet, 60	1	1	..	13.13	14.28	Ferro-f-tab	AE

VITAMIN B12 AND FOLIC ACID

Vitamin B12 (cyanocobalamin and analogues)

HYDROXOCOBALAMIN

Restricted benefit

Pernicious anaemia

Restricted benefit

Proven vitamin B12 deficiencies other than pernicious anaemia

Restricted benefit

Anaemias associated with vitamin B12 deficiency

Clinical criteria:

Patient must have had a gastrectomy,

AND

The treatment must be for prophylaxis.

Note

One injection of hydroxocobalamin 1 mg every three months provides appropriate maintenance therapy in vitamin B12 deficiencies.

Note

Pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as acetate) in 1 mL and pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as chloride) in 1 mL are equivalent for the purposes of substitution.

2162T NP	hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules	1	..	..	11.67	12.82	^a Vita-B12	GH
9048F NP	hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules	1	..	..	11.67	12.82	^a Hydroxo-B12	AS
							^a Neo-B12	HH

Folic acid and derivatives

FOLIC ACID

Note

The 5 mg strength tablet should be used in malabsorption states only.

1437P NP	folic acid 5 mg tablet, 100	2	1	..	*14.36	15.51	Megafof 5	AF

FOLIC ACID

2958Q NP	folic acid 500 microgram tablet, 100	2	..	..	*11.68	12.83	^a Foltabs 500	PP
							^a Megafof 0.5	AF

BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS

BLOOD AND RELATED PRODUCTS

Blood substitutes and plasma protein fractions

GELATIN-SUCCINYLATED

8444K NP	gelatin-succinylated 20 g/500 mL injection, 1 x 500 mL bag	3	..	..	*46.09	37.70	Gelofusine	BR

PENTASTARCH + SODIUM CHLORIDE

9487H NP	HYDROXYETHYL STARCH 130/0.4 I.V. infusion 30 g per 500 mL, 500 mL, 1	3	..	..	*46.09	37.70	Voluven 6%	PK

I.V. SOLUTIONS

Solutions for parenteral nutrition

GLUCOSE

2245E NP	glucose 5% (50 g/1000 mL) injection, 1 x 1000 mL bag	5	1	..	*15.96	17.11	Baxter Healthcare Pty Ltd	BX
5106R DP	glucose 5% (50 g/1000 mL) injection, 1 x 1000 mL bag	5	..	..	*15.96	17.11	Baxter Healthcare Pty Ltd	BX

Solutions affecting the electrolyte balance

BLOOD AND BLOOD FORMING ORGANS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
LACTATE + SODIUM CHLORIDE + POTASSIUM CHLORIDE + CALCIUM CHLORIDE DIHYDRATE								
2286H NP	lactate sodium 0.322% (3.22 g/1000 mL) + sodium chloride 0.6% (6 g/1000 mL) + potassium chloride 0.04% (400 mg/1000 mL) + calcium chloride dihydrate 0.027% (270 mg/1000 mL) injection, 1 x 1000 mL bag	5	1	..	*14.66	15.81	Baxter Healthcare Pty Ltd	BX
SODIUM CHLORIDE								
2264E NP	sodium chloride 0.9% (9 g/1000 mL) injection, 1 x 1000 mL bag	5	1	..	*15.21	16.36	Baxter Healthcare Pty Ltd	BX
5212H DP	sodium chloride 0.9% (9 g/1000 mL) injection, 1 x 1000 mL bag	5	..	..	*15.21	16.36	Baxter Healthcare Pty Ltd	BX
SODIUM CHLORIDE + GLUCOSE								
2281C NP	sodium chloride 0.18% (1.8 g/1000 mL) + glucose 4% (40 g/1000 mL) injection, 1 x 1000 mL bag	5	1	..	*23.86	25.01	Baxter Healthcare Pty Ltd	BX
5214K DP	sodium chloride 0.18% (1.8 g/1000 mL) + glucose 4% (40 g/1000 mL) injection, 1 x 1000 mL bag	5	..	..	*23.86	25.01	Baxter Healthcare Pty Ltd	BX
SODIUM GLUCONATE + SODIUM CHLORIDE + POTASSIUM CHLORIDE + MAGNESIUM CHLORIDE + SODIUM ACETATE TRIHYDRATE + GLUCOSE								
3199J NP	sodium gluconate 5.02 g/1000 mL + sodium chloride 5.26 g/1000 mL + potassium chloride 370 mg/1000 mL + magnesium chloride 300 mg/1000 mL + sodium acetate trihydrate 3.68 g/1000 mL + glucose 5% (50 g/1000 mL) injection, 1 x 1000 mL bag	2	1	..	*22.30	23.45	Plasma-Lyte 148	BX

OTHER HEMATOLOGICAL AGENTS

OTHER HEMATOLOGICAL AGENTS

Drugs used in hereditary angioedema

ICATIBANT

Authority required

Initial supply for anticipated emergency treatment of an acute attack of hereditary angioedema in a patient with confirmed diagnosis of C1-esterase inhibitor deficiency who has been assessed to be at significant risk of an acute attack of hereditary angioedema by or in consultation with a clinical immunologist, respiratory physician, specialist allergist or general physician experienced in the management of patients with hereditary angioedema.

The name of the specialist consulted must be provided at the time of application for initial supply.

The name of the Approved Pathology Authority and date of the diagnosing pathology test must be included in the authority application

Authority required

Continuing supply for anticipated emergency treatment of an acute attack of hereditary angioedema, where the patient has previously been issued with an authority prescription for this drug

Note

Icatibant should be provided in the framework of a comprehensive hereditary angioedema prophylaxis program and an emergency Action Plan including training in recognition of the symptoms of hereditary angioedema and the self-administration of icatibant. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au)

1976B	ICATIBANT Injection 30 mg (as acetate) in 3 mL single use pre-filled syringe, 1	1	1	..	2571.70	37.70	Firazyr	ZI

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

CARDIOVASCULAR SYSTEM

CARDIAC THERAPY

CARDIAC GLYCOSIDES

Digitalis glycosides

DIGOXIN

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1322N NP	digoxin 250 microgram tablet, 100	1	1	..	11.05	12.20	^a Sigmaxin	FM
				^b 2.94	13.99	12.20	^a Lanoxin	QA
3164M NP	digoxin 50 microgram/mL oral liquid, 60 mL	2	3	..	*41.46	37.70	Lanoxin	QA
2605D NP	digoxin 62.5 microgram tablet, 200	1	1	..	10.76	11.91	^a Sigmaxin-PG	FM
				^b 2.95	13.71	11.91	^a Lanoxin-PG	QA

ANTIARRHYTHMICS, CLASS I AND III

Antiarrhythmics, class Ia

DISOPYRAMIDE

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2923W NP	disopyramide 100 mg capsule, 100	1	5	..	29.47	30.62	Rythmodan	SW
2924X NP	disopyramide 150 mg capsule, 100	1	5	..	46.85	37.70	Rythmodan	SW

Antiarrhythmics, class Ib

LIGNOCAINE

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2876J NP	lignocaine hydrochloride anhydrous 500 mg/5 mL injection, 10 x 5 mL ampoules	1	..	..	29.93	31.08	Xylocard 500	AP

Antiarrhythmics, class Ic

FLECAINIDE

Restricted benefit

Serious supra-ventricular cardiac arrhythmias

Restricted benefit

Serious ventricular cardiac arrhythmias where treatment is initiated in a hospital (in-patient or out-patient)

Caution

Flecainide acetate should be avoided in patients with poor cardiac function.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1090J NP	flecainide acetate 100 mg tablet, 60	1	5	..	45.03	37.70	^a Flecatab	AF
							^a Tambocor	IA
1088G NP	flecainide acetate 50 mg tablet, 60	1	5	..	38.07	37.70	Tambocor	IA

Antiarrhythmics, class III

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
AMIODARONE							
<u>Restricted benefit</u>							
Severe cardiac arrhythmias							
<u>Caution</u>							
Amiodarone hydrochloride has been reported to cause frequent and potentially serious toxicity.							
Regular monitoring of hepatic and thyroid function is recommended.							
<u>Note</u>							
Shared Care Model:							
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
2344J NP	amiodarone hydrochloride 100 mg tablet, 30	1	5	..	11.76	12.91	^a Aratac 100 AF
2343H NP	amiodarone hydrochloride 200 mg tablet, 30	1	5	..	15.66	16.81	^a Cordarone X 100 SW ^a Amiodarone Actavis GN
							^a Amiodarone Sandoz SZ ^a Aratac 200 AF ^a Chem mart Amiodarone CH ^a Cordarone X 200 SW ^a GenRx Amiodarone GX ^a Rithmik 200 QA ^a Terry White Chemists Amiodarone TW
SOTALOL							
<u>Restricted benefit</u>							
Severe cardiac arrhythmias							
<u>Note</u>							
Shared Care Model:							
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
2043M NP	sotalol hydrochloride 160 mg tablet, 60	1	5	..	15.81	16.96	^a APO-Sotalol TX
							^a Cardol AF ^a Chem mart Sotalol CH ^a GenRx Sotalol GX ^a Solavert QA ^a Sotalol Sandoz SZ ^a Terry White Chemists Sotalol TW
8398B NP	sotalol hydrochloride 80 mg tablet, 60	1	5	..	^B 3.32 19.13 10.98	16.96 12.13	^a Sotacor FM ^a APO-Sotalol TX
							^a GenRx Sotalol GX ^a Solavert QA ^a Sotalol Sandoz SZ ^B 3.31 14.29 12.13 ^a Sotacor FM

CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES

Adrenergic and dopaminergic agents

ADRENALINE							
1016L NP	adrenaline 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules	1	1	..	20.68	21.83	Link Medical Products Pty Ltd LM
5004J DP	adrenaline 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules	1	..	..	20.68	21.83	Link Medical Products Pty Ltd LM

ADRENALINE

Authority required

Initial sole PBS-subsidised supply for anticipated emergency treatment of acute allergic reactions with anaphylaxis in a patient who has been assessed to be at significant risk of anaphylaxis by, or in consultation with, a clinical immunologist, allergist, paediatrician or respiratory physician. The name of the specialist consulted must be provided at the time of application for initial supply

Authority required

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Initial sole PBS-subsidised supply for anticipated emergency treatment of acute allergic reactions with anaphylaxis in a patient who has been discharged from hospital or an emergency department after treatment with adrenaline for acute allergic reaction with anaphylaxis							
	Authority required							
	Continuing sole PBS-subsidised supply for anticipated emergency treatment of acute allergic reactions with anaphylaxis, where the patient has previously been issued with an authority prescription for this drug							
	Caution							
	EpiPen and Anapen products have different administration techniques and should not be prescribed to the same patient without training in their use.							
	Note							
	The auto-injector should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the auto-injector device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au .)							
	Note							
	Authority approvals will be limited to a maximum quantity of 2 auto-injectors (Anapen or EpiPen) at any one time.							
	No repeats will be issued.							
3408J NP	adrenaline 150 microgram/0.3 mL injection, 1 x 0.3 mL syringe	1	..	..	106.34	37.70	Anapen Junior	LM
8697R NP	adrenaline 150 microgram/0.3 mL injection, 1 x 0.3 mL syringe	1	..	..	106.34	37.70	EpiPen Jr.	AL
3409K NP	adrenaline 300 microgram/0.3 mL injection, 1 x 0.3 mL syringe	1	..	..	106.34	37.70	Anapen	LM
8698T NP	adrenaline 300 microgram/0.3 mL injection, 1 x 0.3 mL syringe	1	..	..	106.34	37.70	EpiPen	AL

VASODILATORS USED IN CARDIAC DISEASES

Organic nitrates

GLYCERYL TRINITRATE

1516T NP	glyceryl trinitrate 10 mg/24 hours patch, 30	1	5	..	31.22	32.37	Transiderm-Nitro 50	NV
8011P NP	glyceryl trinitrate 10 mg/24 hours patch, 30	1	5	..	31.22	32.37	Nitro-Dur 10	MK
8028M NP	glyceryl trinitrate 10 mg/24 hours patch, 30	1	5	..	31.22	32.37	Minitran 10	IA
8026K NP	glyceryl trinitrate 15 mg/24 hours patch, 30	1	5	..	31.22	32.37	Nitro-Dur 15	MK
8119H NP	glyceryl trinitrate 15 mg/24 hours patch, 30	1	5	..	31.22	32.37	Minitran 15	IA
1515R NP	glyceryl trinitrate 5 mg/24 hours patch, 30	1	5	..	25.41	26.56	Transiderm-Nitro 25	NV
8010N NP	glyceryl trinitrate 5 mg/24 hours patch, 30	1	5	..	25.41	26.56	Nitro-Dur 5	MK
8027L NP	glyceryl trinitrate 5 mg/24 hours patch, 30	1	5	..	25.41	26.56	Minitran 5	IA
1459T NP	glyceryl trinitrate 600 microgram tablet: sublingual, 100 tablets	1	5	..	15.17	16.32	^a Lycinate	FM
				^b 2.94	18.11	16.32	^a Anginine Stabilised	QA
5108W DP	glyceryl trinitrate 600 microgram tablet: sublingual, 100 tablets	1	..	..	15.17	16.32	^a Lycinate	FM
				^b 2.94	18.11	16.32	^a Anginine Stabilised	QA

GLYCERYL TRINITRATE

Note

The spray should not be inhaled.

8171C NP	glyceryl trinitrate 400 microgram/actuation spray, 200 actuations	1	5	..	20.47	21.62	Nitrolingual Pumpspray	SW
ISOSORBIDE DINITRATE								
2588F NP	isosorbide dinitrate 5 mg tablet: sublingual, 100	2	2	..	*14.90	16.05	Isordil Sublingual	QA
ISOSORBIDE MONONITRATE								
8273K NP	isosorbide mononitrate 120 mg tablet: modified release, 30 tablets	1	5	..	16.17	17.32	^a Monodur 120 mg	PM
				^b 3.03	19.20	17.32	^a Imdur 120 mg	AP
1558B	isosorbide mononitrate 60 mg tablet:	1	5	..	10.74	11.89	^a Chem mart Isosorbide	CH

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
NP	modified release, 30 tablets						Mononitrate	
							a Duride	AF
							a GenRx Isosorbide	GX
							Mononitrate	
							a Imtrate 60 mg	GN
							a Isomonit	SZ
							a Isosorbide AN	EA
							a Terry White Chemists	TW
							Isosorbide	
				^B 2.23	12.97	11.89	a Monodur 60 mg	PM
				^B 3.05	13.79	11.89	a Imdur Durule	AP

Other vasodilators used in cardiac diseases

NICORANDIL

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8228C NP	nicorandil 10 mg tablet, 60	±1	5	..	22.84	23.99	a Ikorel	SW
8229D NP	nicorandil 20 mg tablet, 60	±1	5	..	29.15	30.30	a Ikotab	QA
							a Ikorel	SW
							a Ikotab	QA

PERHEXILINE

Authority required (STREAMLINED)

1023

Angina not responding to other therapy

Caution

Regular monitoring of drug serum levels is recommended.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1822X NP	perhexiline maleate 100 mg tablet, 100	1	5	..	62.96	37.70	Pexsig	QA

OTHER CARDIAC PREPARATIONS

Other cardiac preparations

IVABRADINE

Authority required

Chronic heart failure

Clinical criteria:

Patient must be symptomatic with NYHA classes II or III,

AND

Patient must be in sinus rhythm,

AND

Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 35%,

AND

Patient must have a resting heart rate at or above 77 bpm at the time ivabradine treatment is initiated,

AND

Patient must receive concomitant optimal standard chronic heart failure treatment, which must include the maximum tolerated dose of a beta-blocker, unless contraindicated or not tolerated.

Resting heart rate should be measured by ECG after 5 minutes rest.

The ECG result must be documented in the patient's medical records when treatment is initiated.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
10012Y NP	ivabradine 5 mg tablet, 56	1	5	..	56.44	37.70	Coralan	SE
2960T NP	ivabradine 7.5 mg tablet, 56	1	5	..	56.44	37.70	Coralan	SE

ANTIHYPERTENSIVES

ANTIADRENERGIC AGENTS, CENTRALLY ACTING

Methyldopa

METHYLDOPA

1629R NP	methyldopa 250 mg tablet, 100	1	5	..	16.88	18.03	^a Hydopa	AF
				^b 3.54	20.42	18.03	^a Aldomet	AS

Imidazoline receptor agonists

CLONIDINE

3145M NP	clonidine hydrochloride 100 microgram tablet, 100	1	5	..	29.22	30.37	Catapres 100	BY
3141H NP	clonidine hydrochloride 150 microgram tablet, 100	1	5	..	37.78	37.70	Catapres	BY

MOXONIDINE

Restricted benefit

Hypertension in patients receiving concurrent antihypertensive therapy

9019Q NP	moxonidine 200 microgram tablet, 30	1	5	..	19.87	21.02	Physiotens	GO
9020R NP	moxonidine 400 microgram tablet, 30	1	5	..	29.12	30.27	Physiotens	GO

ANTIADRENERGIC AGENTS, PERIPHERALLY ACTING

Alpha-adrenoreceptor antagonists

PRazosin

1479W NP	prazosin 1 mg tablet, 100	1	5	..	11.00	12.15	^a APO-Prazosin	TX
							^a Chem mart Prazosin	CH
							^a Minipress	PF
							^a Terry White Chemists Prazosin	TW
1480X NP	prazosin 2 mg tablet, 100	1	5	..	13.52	14.67	^a APO-Prazosin	TX
							^a Chem mart Prazosin	CH
							^a Minipress	PF
							^a Terry White Chemists Prazosin	TW
1478T NP	prazosin 5 mg tablet, 100	1	5	..	18.90	20.05	^a APO-Prazosin	TX
							^a Chem mart Prazosin	CH
							^a Minipress	PF
							^a Terry White Chemists Prazosin	TW

ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON

Hydralazine derivatives

HYDRALAZINE

1640H NP	hydralazine hydrochloride 25 mg tablet, 100	2	2	..	*17.64	18.79	Alphapress 25	AF
1639G NP	hydralazine hydrochloride 50 mg tablet, 100	2	2	..	*19.36	20.51	Alphapress 50	AF

Pyrimidine derivatives

MINOXIDIL

Authority required (STREAMLINED)

2759

Severe refractory hypertension. Treatment must be initiated by a consultant physician

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2313R NP	minoxidil 10 mg tablet, 100	1	5	..	60.61	37.70	Loniten	PF

DIURETICS

LOW-CEILING DIURETICS, THIAZIDES

Thiazides, plain

HYDROCHLOROTHIAZIDE

1484D NP	hydrochlorothiazide 25 mg tablet, 100	1	1	..	21.58	22.73	Dithiazide	PL

LOW-CEILING DIURETICS, EXCL. THIAZIDES

Sulfonamides, plain

CHLORTHALIDONE

1585K NP	chlorthalidone 25 mg tablet, 50	2	1	..	*17.92	19.07	Hygroton 25	LM

INDAPAMIDE

8532C NP	indapamide hemihydrate 1.5 mg tablet: modified release, 90 tablets	1	1	..	19.64	20.79	^a APO-Indapamide SR	TX
							^a Chem mart Indapamide SR	CH
							^a Natrilix SR	SE
							^a Odaplix SR	AF
							^a Tenaxil SR	QA
							^a Terry White Chemists Indapamide SR	TW
2436F NP	indapamide hemihydrate 2.5 mg tablet, 90	1	1	..	15.59	16.74	^a Chem mart Indapamide	CH
							^a Dapa-Tabs	AF
							^a GenRx Indapamide	GX
							^a Indapamide AN	EA
							^a Indapamide-GA	GN
							^a Indapamide Sandoz	SZ
							^a Insig	QA
							^a Terry White Chemists Indapamide	TW
				^B 4.11	19.70	16.74	^a Natrilix	SE

HIGH-CEILING DIURETICS

Sulfonamides, plain

FRUSEMIDE

2411X NP	frusemide 10 mg/mL oral liquid, 30 mL	‡1	3	..	25.18	26.33	Lasix	SW
2413B NP	frusemide 20 mg/2 mL injection, 5 x 2 mL ampoules	1	..	..	8.63	9.78	^a Frusemide-Clarix	AE
							^a Frusemide Sandoz	SZ
							^a Lasix	SW
2412Y NP	frusemide 40 mg tablet, 100	1	1	..	8.15	9.30	^a APO-Frusemide	TX
							^a Chem mart Frusemide	CH
							^a Frusax	ER
							^a Frusemide Sandoz	SZ
							^a Frusid	UA
							^a GenRx Frusemide	GX
							^a Terry White Chemists Frusemide	TW
							^a Uremide	AF
							^a Urex	FM
				^B 2.13	10.28	9.30	^a Lasix	SW

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
2415D NP	frusemide 500 mg tablet, 50	1	3	..	14.02	15.17	Urex-Forte	FM
FRUSEMIDE								
Note								
For item codes 2414C and 1810G, pharmaceutical benefits that have the form tablet 20 mg are equivalent for the purposes of substitution.								
2414C NP	frusemide 20 mg tablet, 100	1	1	..	8.29	9.44	^a APO-Frusemide	TX
							^a Chem mart Frusemide	CH
							^a Frusid	GN
							^a GenRx Frusemide	GX
							^a Terry White Chemists Frusemide	TW
1810G NP	frusemide 20 mg tablet, 50	2	1	..	*8.30	9.45	^a Urex-M	FM
				^B 1.68	*9.98	9.45	^a Lasix-M	SW

Aryloxyacetic acid derivatives

ETHACRYNIC ACID

Restricted benefit

Patients hypersensitive to other oral diuretics

8748K NP	ethacrynic acid 25 mg tablet, 100	2	1	..	*197.64	37.70	Edecrin	FK

POTASSIUM-SPARING AGENTS

Aldosterone antagonists

EPLERENONE

Authority required (STREAMLINED)

2637

Heart failure with a left ventricular ejection fraction of 40% or less occurring within 3 to 14 days following an acute myocardial infarction. Treatment with eplerenone must be commenced within 14 days of an acute myocardial infarction.

The date of the acute myocardial infarction and the date of initiation of eplerenone treatment must be documented in the patient's medical records when PBS-subsidised treatment is initiated

Caution

Serum electrolytes should be checked regularly.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8879H NP	eplerenone 25 mg tablet, 30	1	5	..	113.11	37.70	Inspira	PF
8880J NP	eplerenone 50 mg tablet, 30	1	5	..	113.11	37.70	Inspira	PF

SPIRONOLACTONE

Caution

Serum electrolytes should be checked regularly.

Caution

Appropriate contraceptive measures should be taken by women of child-bearing age in whom spironolactone therapy has been initiated.

2340E NP	spironolactone 100 mg tablet, 100	1	5	..	29.46	30.61	^a Spiractin 100	AF
				^B 3.16	32.62	30.61	^a Aldactone	PF
2339D NP	spironolactone 25 mg tablet, 100	1	5	..	12.53	13.68	^a Spiractin 25	AF
				^B 2.59	15.12	13.68	^a Aldactone	PF

DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION

Low-ceiling diuretics and potassium-sparing agents

HYDROCHLOROTHIAZIDE + AMILORIDE

Caution

Serum electrolytes should be checked regularly.

1486F NP	hydrochlorothiazide 50 mg + amiloride hydrochloride 5 mg tablet, 50	2	1	..	*13.84	14.99	Moduretic	AS

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
HYDROCHLOROTHIAZIDE + TRIAMTERENE								
Caution								
Serum electrolytes should be checked regularly.								
1280J NP	hydrochlorothiazide 25 mg + triamterene 50 mg tablet, 100	1	1	..	13.23	14.38	Hydrene 25/50	AF

PERIPHERAL VASODILATORS

PERIPHERAL VASODILATORS

Other peripheral vasodilators

PHENOXYBENZAMINE

Authority required

Phaeochromocytoma

Authority required

Neurogenic urinary retention

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1862B NP	phenoxybenzamine hydrochloride 10 mg capsule, 100	1	5	..	1164.81	37.70	Dibenylene	GH
9286R NP	phenoxybenzamine hydrochloride 10 mg capsule, 100	1	5	..	6860.58	37.70	Dibenzylene	BZ
1166J NP	phenoxybenzamine hydrochloride 10 mg capsule, 30	3	5	..	*205.24	37.70	Dibenylene	GH

BETA BLOCKING AGENTS

BETA BLOCKING AGENTS

Beta blocking agents, non-selective

OXPRENOLOL

2961W NP	oxprenolol hydrochloride 40 mg tablet, 100	1	5	..	48.58	37.70	Corbeton 40	AF

PINDOLOL

3065H NP	pindolol 15 mg tablet, 50	1	5	..	16.26	17.41	Visken 15	NV
3062E NP	pindolol 5 mg tablet, 100	1	5	..	30.77	31.92	Barbloc 5	AF

PROPRANOLOL

2565B NP	propranolol hydrochloride 10 mg tablet, 100	1	5	..	10.53	11.68	Deralin 10	AF
				^B 3.75	14.28	11.68	Inderal	AP
2899N NP	propranolol hydrochloride 160 mg tablet, 50	1	5	..	12.80	13.95	Deralin 160	AF
2566C NP	propranolol hydrochloride 40 mg tablet, 100	1	5	..	10.90	12.05	Deralin 40	AF
				^B 3.75	14.65	12.05	Inderal	AP

Beta blocking agents, selective

ATENOLOL

1081X NP	atenolol 50 mg tablet, 30	1	5	..	8.07	9.22	^a APO-Atenolol	TX
						^a	Atenolol AN	EA
						^a	Atenolol-GA	GN
						^a	Atenolol GH	GQ
						^a	Atenolol Sandoz	SZ
						^a	Chem mart Atenolol	CH
						^a	Noten	AF
						^a	Tenolten 50	DO
						^a	Tensig	QA
						^a	Terry White Chemists	TW

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
				^B 1.96	10.03	9.22	^a Atenolol Tenormin	AP
ATENOLOL <u>Restricted benefit</u> For a patient who is unable to take a solid dose form of atenolol.								
2243C NP	atenolol 50 mg/10 mL oral liquid, 300 mL	‡1	5	..	27.78	28.93	Atenolol-AFT	AE
BISOPROLOL <u>Authority required (STREAMLINED)</u> 3234 Moderate to severe heart failure in a patient stabilised on conventional therapy which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated								
<u>Note</u> Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8606Y NP	bisoprolol fumarate 10 mg tablet, 28	1	5	..	33.83	34.98	^a APO-Bisoprolol	TX
							^a Beprol 10	DO
							^a Bicard 10	QA
							^a Biso 10	GN
							^a Bisoprolol AN	EA
							^a Bisoprolol GH	GQ
							^a Bisoprolol Sandoz	SZ
							^a Bispro 10	AF
							^a Chem mart Bisoprolol	CH
							^a Terry White Chemists	TW
				^B 2.60	36.43	34.98	Bisoprolol	
8604W NP	bisoprolol fumarate 2.5 mg tablet, 28	1	5	..	24.08	25.23	^a Bicor	AL
							^a APO-Bisoprolol	TX
							^a Beprol 2.5	DO
							^a Bicard 2.5	QA
							^a Biso 2.5	GN
							^a Bisoprolol AN	EA
							^a Bisoprolol GH	GQ
							^a Bisoprolol Sandoz	SZ
							^a Bispro 2.5	AF
							^a Chem mart Bisoprolol	CH
							^a Terry White Chemists	TW
				^B 2.55	26.63	25.23	Bisoprolol	
8605X NP	bisoprolol fumarate 5 mg tablet, 28	1	5	..	28.41	29.56	^a Bicor	AL
							^a APO-Bisoprolol	TX
							^a Beprol 5	DO
							^a Bicard 5	QA
							^a Biso 5	GN
							^a Bisoprolol AN	EA
							^a Bisoprolol GH	GQ
							^a Bisoprolol Sandoz	SZ
							^a Bispro 5	AF
							^a Chem mart Bisoprolol	CH
							^a Terry White Chemists	TW
				^B 2.55	30.96	29.56	Bisoprolol	
							^a Bicor	AL

METOPROLOL SUCCINATE
Authority required (STREAMLINED)
3234

Moderate to severe heart failure in a patient stabilised on conventional therapy which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated

Note

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
Continuing Therapy Only:							
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
8735R NP	METOPROLOL SUCCINATE Tablet 190 mg (controlled release), 30	1	5	..	93.43	37.70	^a Metrol-XL 190 QA
							^a Minax XL AF
							^a Toprol-XL 190 AP
8732N NP	METOPROLOL SUCCINATE Tablet 23.75 mg (controlled release), 15	1	..	..	19.04	20.19	^a Metrol-XL 23.75 QA
							^a Minax XL AF
							^a Toprol-XL 23.75 AP
8733P NP	METOPROLOL SUCCINATE Tablet 47.5 mg (controlled release), 30	1	5	..	62.24	37.70	^a Metrol-XL 47.5 QA
							^a Minax XL AF
							^a Toprol-XL 47.5 AP
8734Q NP	METOPROLOL SUCCINATE Tablet 95 mg (controlled release), 30	1	5	..	76.09	37.70	^a Metrol-XL 95 QA
							^a Minax XL AF
							^a Toprol-XL 95 AP
METOPROLOL TARTRATE							
1325R NP	METOPROLOL TARTRATE Tablet 100 mg, 60	1	5	..	10.23	11.38	^b APO-Metoprolol TX
							^b Chem mart Metoprolol CH
							^b GenRx Metoprolol GX
							^b Metoprolol Sandoz SZ
							^b Metrol 100 QA
							^b Minax 100 AF
							^b Terry White Chemists Metoprolol TW
							^a Metatar FM
							^a Metoprolol Actavis GN
							^a Metoprolol AN EA
							^a Mistrom ER
				^B 2.00	12.23	11.38	^a Lopresor 100 NV
				^B 3.76	13.99	11.38	^b Betaloc AP
1324Q NP	METOPROLOL TARTRATE Tablet 50 mg, 100	1	5	..	9.49	10.64	^a Metatar FM
							^a Metoprolol Actavis GN
							^a Metoprolol AN EA
							^a Mistrom ER
							^b APO-Metoprolol TX
							^b Chem mart Metoprolol CH
							^b GenRx Metoprolol GX
							^b Metoprolol Sandoz SZ
							^b Metrol 50 QA
							^b Minax 50 AF
							^b Terry White Chemists Metoprolol TW
				^B 2.01	11.50	10.64	^a Lopresor 50 NV
				^B 3.76	13.25	10.64	^b Betaloc AP

NEBIVOLOL

Authority required (STREAMLINED)

3234

Moderate to severe heart failure in a patient stabilised on conventional therapy which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

9316H NP	nebivolol 1.25 mg tablet, 28	2	5	..	*50.96	37.70	Nebilet FK
9312D	nebivolol 10 mg tablet, 28	1	5	..	68.36	37.70	Nebilet FK

8257N NP	carvedilol 12.5 mg tablet, 60	1	5	..	25.53	26.68	a	APO-Carvedilol	TX
							a	Carvedilol AN	EA
							a	Carvedilol generichealth	GQ
							a	Carvedilol Sandoz	SZ
							a	Chem mart Carvedilol 12.5 mg	CH
							a	Dicarz	AF
							a	Dilatrend 12.5	RO
							a	GN-Carvedilol	GN
							a	Terry White Chemists Carvedilol 12.5 mg	TW
							a	Vedilol 12.5	QA
							a	Volirop 12.5	DO
8258P NP	carvedilol 25 mg tablet, 60	1	5	..	30.23	31.38	a	APO-Carvedilol	TX
							a	Carvedilol AN	EA
							a	Carvedilol generichealth	GQ
							a	Carvedilol Sandoz	SZ
							a	Chem mart Carvedilol 25 mg	CH
							a	Dicarz	AF
							a	Dilatrend 25	RO
							a	GN-Carvedilol	GN
							a	Terry White Chemists Carvedilol 25 mg	TW
							a	Vedilol 25	QA
							a	Volirop 25	DO
8255L NP	carvedilol 3.125 mg tablet, 30	1	..	..	9.93	11.08	a	APO-Carvedilol	TX
							a	Carvedilol AN	EA
							a	Chem mart Carvedilol 3.125 mg	CH
							a	Dilatrend 3.125	RO
							a	GN-Carvedilol	GN
							a	Terry White Chemists Carvedilol 3.125 mg	TW
							a	Vedilol 3.125	QA
							a	Volirop 3.125	DO
8256M NP	carvedilol 6.25 mg tablet, 60	1	5	..	21.77	22.92	a	APO-Carvedilol	TX
							a	Carvedilol AN	EA
							a	Carvedilol generichealth	GQ
							a	Carvedilol Sandoz	SZ
							a	Chem mart Carvedilol 6.25 mg	CH

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							^a Dicarz	AF
							^a Dilatrend 6.25	RO
							^a GN-Carvedilol	GN
							^a Terry White Chemists Carvedilol 6.25 mg	TW
							^a Vedilol 6.25	QA
							^a Volirop 6.25	DO
	LABETALOL							
1566K NP	labetalol hydrochloride 100 mg tablet, 100	1	5	.. ^B 3.13	15.62 18.75	16.77	^a Presolol 100	AF
1567L NP	labetalol hydrochloride 200 mg tablet, 100	1	5	.. ^B 3.14	21.34 24.48	22.49	^a Trandate ^a Presolol 200	QA AF
							^a Trandate	QA

CALCIUM CHANNEL BLOCKERS

SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS

Dihydropyridine derivatives

AMLODIPINE

[illegible]

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
2366M NP	felodipine 5 mg tablet: modified release, 30 tablets	1	5	^B 2.75 ..	13.22 12.10	11.62 13.25	^a Plendil ER ^a Felodil XR 5	GX QA
				^B 2.76	14.86	13.25	^a Felodur ER 5 mg ^a Fendex ER ^a Plendil ER	TX AF GX
LERCANIDIPINE								
8534E NP	lercanidipine hydrochloride 10 mg tablet, 28	1	5	..	9.82	10.97	^a APO-Lercanidipine	TX
							^a Chem mart Lercanidipine	CH
							^a Ledip	RA
							^a Lercadip	GN
							^a Lercan	QA
							^a Lercanidipine GH	GQ
							^a Lercanidipine Sandoz	SZ
							^a Terry White Chemists Lercanidipine	TW
				^B 2.98	12.80	10.97	^a Zircol	AF
				..	11.85	13.00	^a Zanicidip	GO
8679T NP	lercanidipine hydrochloride 20 mg tablet, 28	1	5	..	11.85	13.00	^a APO-Lercanidipine	TX
							^a Chem mart Lercanidipine	CH
							^a Ledip	RA
							^a Lercadip	GN
							^a Lercan	QA
							^a Lercanidipine GH	GQ
							^a Lercanidipine Sandoz	SZ
							^a Terry White Chemists Lercanidipine	TW
				^B 2.97	14.82	13.00	^a Zircol	AF
							^a Zanicidip	GO
NIFEDIPINE								
1694E NP	nifedipine 10 mg tablet, 60	1	5	..	13.19	14.34	^a Adefin 10	AF
				^B 1.84	15.03	14.34	^a Adalat 10	BN
1695F NP	nifedipine 20 mg tablet, 60	1	5	..	14.67	15.82	^a Adefin 20	AF
				^B 2.57	17.24	15.82	^a GenRx Nifedipine	GX
8610E NP	nifedipine 20 mg tablet: modified release, 30 tablets	1	5	..	14.98	16.13	^a Adalat 20	BN
1906H NP	nifedipine 30 mg tablet: modified release, 30 tablets	1	5	..	15.65	16.80	^a Addos XR 30	QA
							^a Adefin XL 30	AF
				^B 2.82	18.47	16.80	^a APO-Nifedipine XR	TX
1907J NP	nifedipine 60 mg tablet: modified release, 30 tablets	1	5	..	17.93	19.08	^a Adalat Oros 30	BN
							^a Addos XR 60	QA
							^a Adefin XL 60	AF
				^B 2.99	20.92	19.08	^a APO-Nifedipine XR	TX
							^a Adalat Oros 60	BN

SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS

Phenylalkylamine derivatives

VERAPAMIL

Caution

The myocardial depressant effects of this drug and of beta-blocking drugs are additive.

2206D NP	verapamil hydrochloride 160 mg capsule: modified release, 30 capsules	1	5	..	12.49	13.64	Veracaps SR	QA
2208F NP	verapamil hydrochloride 180 mg tablet: modified release, 30 tablets	1	5	..	13.69	14.84	^a Cordilox 180 SR	GT
				^B 3.50	17.19	14.84	^a Isoptin 180 SR	GO

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
2207E NP	verapamil hydrochloride 240 mg capsule: modified release, 30 capsules	1	5	..	16.09	17.24	Veracaps SR	QA
1241H NP	verapamil hydrochloride 240 mg tablet: modified release, 30 tablets	1	5	..	16.01	17.16	^a Cordilox SR	GT
				^B 3.50	19.51	17.16	^a Isoptin SR	GO
1248Q NP	verapamil hydrochloride 40 mg tablet, 100	1	5	..	12.36	13.51	Anpec 40	AF
1250T NP	verapamil hydrochloride 80 mg tablet, 100	1	5	..	15.35	16.50	^a Anpec 80	AF
				^B 3.49	18.84	16.50	^a Isoptin	GO

Benzothiazepine derivatives

DILTIAZEM

Caution

The myocardial depressant effects of this drug and of beta-blocking drugs are additive.

1312C NP	diltiazem hydrochloride 180 mg capsule: modified release, 30 capsules	1	5	..	15.41	16.56	^a Cardizem CD	SW
							^a Chem mart Diltiazem CD	CH
							^a Diltiazem Sandoz CD	SZ
							^a GenRx Diltiazem CD	GX
							^a Terry White Chemists Diltiazem CD	TW
							^a Vasocardol CD	AV
1313D NP	diltiazem hydrochloride 240 mg capsule: modified release, 30 capsules	1	5	..	18.44	19.59	^a Cardizem CD	SW
							^a Chem mart Diltiazem CD	CH
							^a Diltiazem Sandoz CD	SZ
							^a GenRx Diltiazem CD	GX
							^a Terry White Chemists Diltiazem CD	TW
							^a Vasocardol CD	AV
8480H NP	diltiazem hydrochloride 360 mg capsule: modified release, 30 capsules	1	5	..	22.08	23.23	^a Cardizem CD	SW
							^a Diltiazem Sandoz CD	SZ
							^a Vasocardol CD	AV
1335G NP	diltiazem hydrochloride 60 mg tablet, 90	1	5	..	14.56	15.71	^a Cardizem	SW
							^a Diltiazem Actavis	UA
							^a Diltiazem AN	EA
							^a Diltiazem Sandoz	SZ
							^a Dilzem 60 mg	GN
							^a Vasocardol	AV

AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM

ACE INHIBITORS, PLAIN ***ACE inhibitors, plain***

CAPTOPRIL

Caution

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

1147J NP	captopril 12.5 mg tablet, 90	1	5	..	12.07	13.22	^a Captopril Sandoz	SZ
							^a GenRx Captopril	GX
							^a Zedace	AF
1148K NP	captopril 25 mg tablet, 90	1	5	..	14.45	15.60	^a Captopril Sandoz	SZ
							^a GenRx Captopril	GX
							^a Zedace	AF
				^B 4.47	18.92	15.60	^a Capoten	QA
1149L NP	captopril 50 mg tablet, 90	1	5	..	21.93	23.08	^a Captopril Sandoz	SZ
							^a GenRx Captopril	GX
							^a Zedace	AF

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
				^B 3.46	25.39	23.08	^a Capoten	QA
CAPTOPRIL								
<u>Restricted benefit</u>								
For patients unable to take a solid dose form of an ACE inhibitor								
<u>Caution</u>								
Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.								
8760C NP	captopril 5 mg/mL oral liquid, 95 mL	‡1	5	..	112.16	37.70	Capoten	QA
ENALAPRIL								
<u>Caution</u>								
Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.								
1368B NP	enalapril maleate 10 mg tablet, 30	1	5	..	11.38	12.53	^a Acetec	AL
							^a APO-Enalapril	TX
							^a Auspril	QA
							^a Chem mart Enalapril	CH
							^a Enalapril Actavis	UA
							^a Enalapril AN	EA
							^a Enalapril-GA	GN
							^a Enalapril generichealth	GQ
							^a Enalapril Sandoz	SZ
							^a GenRx Enalapril	GX
							^a Malean	FM
							^a Terry White Chemists Enalapril	TW
1369C NP	enalapril maleate 20 mg tablet, 30	1	5	^B 4.07 ..	15.45 12.65	12.53 13.80	^a Renitec	MK
							^a Acetec	AL
							^a APO-Enalapril	TX
							^a Auspril	QA
							^a Chem mart Enalapril	CH
							^a Enalapril Actavis	UA
							^a Enalapril AN	EA
							^a Enalapril-GA	GN
							^a Enalapril generichealth	GQ
							^a Enalapril Sandoz	SZ
							^a GenRx Enalapril	GX
							^a Malean	FM
							^a Terry White Chemists Enalapril	TW
1370D NP	enalapril maleate 5 mg tablet, 30	1	5	^B 4.05 ..	16.70 9.57	13.80 10.72	^a Renitec 20	MK
							^a Acetec	AL
							^a APO-Enalapril	TX
							^a Auspril	QA
							^a Chem mart Enalapril	CH
							^a Enalapril Actavis	UA
							^a Enalapril AN	EA
							^a Enalapril-GA	GN
							^a Enalapril generichealth	GQ
							^a Enalapril Sandoz	SZ
							^a GenRx Enalapril	GX
							^a Malean	FM
							^a Terry White Chemists Enalapril	TW
FOSINOPRIL								
<u>Caution</u>								
Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.								
1182F NP	fosinopril sodium 10 mg tablet, 30	1	5	..	12.88	14.03	^a APO-Fosinopril	TX
							^a Fosipril 10	QA

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$		Brand Name and Manufacturer				
1183G NP	fosinopril sodium 20 mg tablet, 30	1	5	..	15.91	17.06	^a	GenRx Fosinopril	GX			
							^a	Monace 10	AF			
							^a	Monopril	BQ			
							^a	APO-Fosinopril	TX			
							^a	Fosipril 20	QA			
							^a	GenRx Fosinopril	GX			
							^a	Monace 20	AF			
							^a	Monopril	BQ			
LISINOPRIL												
<u>Caution</u>												
Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.												
2457H NP	lisinopril 10 mg tablet, 30	1	5	..	11.60	12.75	^a	APO-Lisinopril	TX			
							^a	Auro-Lisinopril 10	DO			
							^a	Chem mart Lisinopril	CH			
							^a	Fibsol 10	QA			
							^a	Lisinopril AN	EA			
							^a	Lisinopril-DRLA	RZ			
							^a	Lisinopril-GA	GN			
							^a	Lisinopril generichealth	GQ			
							^a	Lisinopril Sandoz	SZ			
							^a	Terry White Chemists Lisinopril	TW			
							^a	Zinopril 10	AL			
							^a	Zestril	AP			
2458J NP	lisinopril 20 mg tablet, 30	1	5	..	12.87	14.02	^B 2.82	14.42	12.75	^a	Prinivil 10	MK
							^B 3.21	14.81	12.75	^a	APO-Lisinopril	TX
							^a	Auro-Lisinopril 20	DO			
							^a	Chem mart Lisinopril	CH			
2456G NP	lisinopril 5 mg tablet, 30	1	5	..	10.00	11.15	^a	Fibsol 20	QA			
							^a	Lisinopril AN	EA			
							^a	Lisinopril-DRLA	RZ			
							^a	Lisinopril-GA	GN			
							^a	Lisinopril generichealth	GQ			
							^a	Lisinopril Sandoz	SZ			
							^a	Terry White Chemists Lisinopril	TW			
							^a	Zinopril 20	AL			
							^a	Zestril	AP			
							^B 2.81	15.68	14.02	^a	Prinivil 20	MK
							^B 3.21	16.08	14.02	^a	APO-Lisinopril	TX
							^a	Auro-Lisinopril 5	DO			
^a	Chem mart Lisinopril	CH										
^a	Fibsol 5	QA										
^a	Lisinopril AN	EA										
^a	Lisinopril-DRLA	RZ										
^a	Lisinopril-GA	GN										
^a	Lisinopril generichealth	GQ										
^a	Lisinopril Sandoz	SZ										
^a	Terry White Chemists Lisinopril	TW										
^a	Zinopril 5	AL										
^B 2.82	12.82	11.15	^a	Zestril	AP							

PERINDOPRIL

Caution

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Note

Pharmaceutical benefits that have the form perindopril erbumine tablet 8 mg and pharmaceutical benefits that have the form perindopril arginine tablet 10 mg are equivalent for the purposes of substitution.

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
9008D NP	perindopril arginine 10 mg tablet, 30	1	5	..	14.99	16.14	^a Coversyl 10mg	SE
8704D NP	perindopril erbumine 8 mg tablet, 30	1	5	..	14.99	16.14	^a PREXUM 10 ^a APO-Perindopril	RX TX
							^a Blooms the Chemist Perindopril	IB
							^a Chem mart Perindopril	CH
							^a Idaprex 8	SZ
							^a Indopril 8	QA
							^a Indosyl Mono 8	FM
							^a Ozapace	RA
							^a Perindo	AF
							^a Perindopril Actavis 8	UA
							^a Perindopril CH	EA
							^a Perindopril generichealth	GQ
							^a Terry White Chemists Perindopril	TW

PERINDOPRIL

Caution

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Note

Pharmaceutical benefits that have the form perindopril erbumine tablet 2 mg and pharmaceutical benefits that have the form perindopril arginine tablet 2.5 mg are equivalent for the purposes of substitution.

9006B NP	perindopril arginine 2.5 mg tablet, 30	1	5	^a 1.65	11.30	10.80	^a Coversyl 2.5mg	SE
							^a PREXUM 2.5	RX
3050M NP	perindopril erbumine 2 mg tablet, 30	1	5	..	9.65	10.80	^a APO-Perindopril	TX
							^a Blooms the Chemist Perindopril	IB
							^a Chem mart Perindopril	CH
							^a Idaprex 2	SZ
							^a Indopril 2	QA
							^a Indosyl Mono 2	FM
							^a Ozapace	RA
							^a Perindo	AF
							^a Perindopril Actavis 2	UA
							^a Terry White Chemists Perindopril	TW

PERINDOPRIL

Caution

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Note

Pharmaceutical benefits that have the form perindopril erbumine tablet 4 mg and pharmaceutical benefits that have the form perindopril arginine tablet 5 mg are equivalent for the purposes of substitution.

9007C NP	perindopril arginine 5 mg tablet, 30	1	5	..	12.14	13.29	^a Coversyl 5mg	SE
							^a PREXUM 5	RX
3051N NP	perindopril erbumine 4 mg tablet, 30	1	5	..	12.14	13.29	^a APO-Perindopril	TX
							^a Blooms the Chemist Perindopril	IB
							^a Chem mart Perindopril	CH
							^a Idaprex 4	SZ
							^a Indopril 4	QA
							^a Indosyl Mono 4	FM
							^a Ozapace	RA
							^a Perindo	AF
							^a Perindopril Actavis 4	UA
							^a Perindopril CH	EA
							^a Perindopril	GQ

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							generichealth Terry White Chemists Perindopril	TW
	QUINAPRIL							
	Caution							
	Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.							
1969P NP	quinapril 10 mg tablet, 30	1	5	..	11.90	13.05	^a Acquin Aspen 10	AS
							^a APO-Quinapril	TX
							^a Aquinafil	GN
							^a Qpril 10	AF
				^B 1.30	13.20	13.05	^a Accupril	PF
1970Q NP	quinapril 20 mg tablet, 30	1	5	..	13.12	14.27	^a Acquin Aspen 20	AS
							^a APO-Quinapril	TX
							^a Aquinafil	GN
							^a Qpril 20	AF
							^a Quinapril-GA	UA
							^a Quinapril generichealth	GQ
				^B 1.30	14.42	14.27	^a Accupril	PF
1968N NP	quinapril 5 mg tablet, 30	1	5	..	10.36	11.51	^a Acquin Aspen 5	AS
							^a APO-Quinapril	TX
							^a Aquinafil	GN
							^a Qpril 5	AF
				^B 1.30	11.66	11.51	^a Accupril	PF
	RAMIPRIL							
	Caution							
	Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.							
	Note							
	Pharmaceutical benefits that have the form ramipril tablet 1.25 mg and pharmaceutical benefits that have the form ramipril capsule 1.25 mg are equivalent for the purposes of substitution.							
9120B NP	ramipril 1.25 mg capsule, 30	1	5	..	8.55	9.70	^a APO-Ramipril	TX
							^a Chem mart Ramipril	CH
							^a Ramipril-GA	GN
							^a Terry White Chemists Ramipril	TW
							^a Tryzan Caps 1.25	AF
							^a Vascalace Caps 1.25	DO
1944H NP	ramipril 1.25 mg tablet, 30	1	5	..	8.55	9.70	^a APO-Ramipril	TX
							^a Chem mart Ramipril	CH
							^a Ramace 1.25 mg	AV
							^a Ramipril AN	EA
							^a Ramipril Sandoz	SZ
							^a Ramipril Winthrop	WA
							^a Terry White Chemists Ramipril	TW
							^a Tritace 1.25 mg	SW
							^a Tryzan Tabs 1.25	AF
							^a Vascalace 1.25	DO
	RAMIPRIL							
	Caution							
	Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.							
	Note							
	Pharmaceutical benefits that have the form ramipril tablet 10 mg and pharmaceutical benefits that have the form ramipril capsule 10 mg are equivalent for the purposes of substitution.							
8470T NP	ramipril 10 mg capsule, 30	1	5	..	12.56	13.71	^a APO-Ramipril	TX
							^a Chem mart Ramipril	CH

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
1316G NP	ramipril 10 mg tablet, 30	1	5	..	12.56	13.71	a GenRx Ramipril	GX
							a Pharmacor Ramipril 10	CR
							a Prilace 10	QA
							a Ramace 10 mg	AV
							a Ramipril CH	EA
							a Ramipril-GA	GN
							a Ramipril generichealth	GQ
							a Ramipril Sandoz	SZ
							a Ramipril Winthrop	WA
							a Terry White Chemists Ramipril	TW
							a Tritace 10 mg	SW
							a Tryzan Caps 10	AF
							a Vascalace Caps 10	DO
							a APO-Ramipril	TX
							a Chem mart Ramipril	CH
							a Ramipril AN	EA
							a Ramipril RBX Tabs	RA
							a Ramipril Sandoz	SZ
							a Ramipril Winthrop	WA
							a Terry White Chemists Ramipril	TW
							a Tritace	SW
							a Tryzan Tabs 10	AF
							a Vascalace 10	DO

RAMIPRIL

Caution

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Note

Pharmaceutical benefits that have the form ramipril tablet 2.5 mg and pharmaceutical benefits that have the form ramipril capsule 2.5 mg are equivalent for the purposes of substitution.

9121C NP	ramipril 2.5 mg capsule, 30	1	5	..	9.38	10.53	a APO-Ramipril	TX
							a Chem mart Ramipril	CH
							a Ramipril-GA	GN
							a Ramipril generichealth	GQ
							a Terry White Chemists Ramipril	TW
							a Tryzan Caps 2.5	AF
1945J NP	ramipril 2.5 mg tablet, 30	1	5	..	9.38	10.53	a Vascalace Caps 2.5	DO
							a APO-Ramipril	TX
							a Chem mart Ramipril	CH
							a Prilace 2.5	QA
							a Ramace 2.5 mg	AV
							a Ramipril AN	EA
							a Ramipril RBX Tabs	RA
							a Ramipril Sandoz	SZ
							a Ramipril Winthrop	WA
							a Terry White Chemists Ramipril	TW
							a Tritace 2.5 mg	SW
							a Tryzan Tabs 2.5	AF
							a Vascalace 2.5	DO

RAMIPRIL

Caution

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

8668F NP	ramipril 2.5 mg tablet [7 tablets] (&) ramipril 5 mg tablet [21 tablets] (&) ramipril 10 mg capsule [10 capsules], 1 pack	‡1	..	..	12.15	13.30	Tritace Titration Pack	SW

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
RAMIPRIL							
<u>Caution</u>							
Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.							
<u>Note</u>							
Pharmaceutical benefits that have the form ramipril tablet 5 mg and pharmaceutical benefits that have the form ramipril capsule 5 mg are equivalent for the purposes of substitution.							
9122D NP	ramipril 5 mg capsule, 30	1	5	..	10.05	11.20	a APO-Ramipril TX a Chem mart Ramipril CH a Pharmacor Ramipril 5 CR a Ramipril-GA GN a Ramipril generichealth GQ a Terry White Chemists Ramipril TW a Tryzan Caps 5 AF a Vascalace Caps 5 DO a APO-Ramipril TX
1946K NP	ramipril 5 mg tablet, 30	1	5	..	10.05	11.20	a Chem mart Ramipril CH a Prilace 5 QA a Ramace 5 mg AV a Ramipril AN EA a Ramipril RBX Tabs RA a Ramipril Sandoz SZ a Ramipril Winthrop WA a Terry White Chemists Ramipril TW a Tritace 5 mg SW a Tryzan Tabs 5 AF a Vascalace 5 DO
TRANDOLAPRIL							
<u>Caution</u>							
Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.							
2792Y NP	trandolapril 1 mg capsule, 28	1	5	..	11.33	12.48	a APO-Trandolapril TX a Dolapril 1 QA a Tranalpha AF a Trandolapril-DP GN a Gopten GO a APO-Trandolapril TX
2793B NP	trandolapril 2 mg capsule, 28	1	5	..	12.26	13.41	a Dolapril 2 QA a Tranalpha AF a Trandolapril-DP GN a Gopten GO a APO-Trandolapril TX
8758Y NP	trandolapril 4 mg capsule, 28	1	5	..	17.10	18.25	a Dolapril 4 QA a Tranalpha AF a Trandolapril-DP GN a Gopten GO a APO-Trandolapril TX
2791X NP	trandolapril 500 microgram capsule, 28	1	5	..	8.47	9.62	a Dolapril 0.5 QA a Tranalpha AF a Trandolapril-DP GN a Gopten GO a APO-Trandolapril TX
				^B 3.11	11.58	9.62	a Gopten GO

ACE INHIBITORS, COMBINATIONS

ACE inhibitors and diuretics

ENALAPRIL + HYDROCHLOROTHIAZIDE

Restricted benefit

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Hypertension							
	Clinical criteria:							
	The treatment must not be for the initiation of anti-hypertensive therapy,							
	AND							
	The condition must be inadequately controlled with an ACE inhibitor; OR							
	The condition must be inadequately controlled with a thiazide diuretic.							
	Caution							
	Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.							
8477E NP	enalapril maleate 20 mg + hydrochlorothiazide 6 mg tablet, 30	1	5	..	27.94	29.09	^a Enalapril/HCT Sandoz	SZ
							^a Renitec Plus 20/6	MK
	FOSINOPRIL + HYDROCHLOROTHIAZIDE							
	Restricted benefit							
	Hypertension							
	Clinical criteria:							
	The treatment must not be for the initiation of anti-hypertensive therapy,							
	AND							
	The condition must be inadequately controlled with an ACE inhibitor; OR							
	The condition must be inadequately controlled with a thiazide diuretic.							
	Caution							
	Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.							
8400D NP	fosinopril sodium 10 mg + hydrochlorothiazide 12.5 mg tablet, 30	1	5	..	21.66	22.81	^a APO-Fosinopril HCTZ 10/12.5	TX
							^a Monoplus 10/12.5	BQ
8401E NP	fosinopril sodium 20 mg + hydrochlorothiazide 12.5 mg tablet, 30	1	5	..	28.64	29.79	^a APO-Fosinopril HCTZ 20/12.5	TX
							^a Fosetic 20/12.5	ZP
							^a Fosinopril/HCT Actavis 20/12.5	UA
							^a Monoplus 20/12.5	BQ
	PERINDOPRIL + INDAPAMIDE							
	Caution							
	Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.							
2190G NP	perindopril arginine 2.5 mg + indapamide hemihydrate 0.625 mg tablet, 30	1	5	..	12.56	13.71	Coversyl Plus LD 2.5mg/0.625mg	SE
	PERINDOPRIL + INDAPAMIDE							
	Restricted benefit							
	Hypertension							
	Clinical criteria:							
	The treatment must not be for the initiation of anti-hypertensive therapy,							
	AND							
	The condition must be inadequately controlled with an ACE inhibitor; OR							
	The condition must be inadequately controlled with a thiazide-like diuretic.							
	Caution							
	Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.							
	Note							
	Pharmaceutical benefits that have the form perindopril with indapamide hemihydrate tablet (containing 4 mg perindopril erbumine-1.25 mg indapamide hemihydrate) and pharmaceutical benefits that have the form perindopril with indapamide hemihydrate tablet (containing 5 mg perindopril arginine-1.25 mg indapamide hemihydrate) are equivalent for the purposes of substitution.							
2845R NP	perindopril arginine 5 mg + indapamide hemihydrate 1.25 mg tablet, 30	1	5	..	19.80	20.95	^a Coversyl Plus 5mg/1.25mg	SE
							^a Prexum Combi 5/1.25	RX
8449Q NP	perindopril erbumine 4 mg + indapamide hemihydrate 1.25 mg	1	5	..	19.80	20.95	^a Chem mart Perindopril/ Indapamide 4/1.25	CH

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	tablet, 30							
							a GenRx Perindopril/Indapamide 4/1.25	GX
							a Idaprex Combi 4/1.25	SZ
							a Indosyl Combi 4/1.25	QA
							a Perindo Combi 4/1.25	AF
							a Perindopril/Indapamide GH 4/1.25	GQ
							a Perindopril and Indapamide CH 4/1.25	EA
							a Perindopril Combi Actavis 4/1.25	GN
							a Terry White Chemists Perindopril/Indapamide 4/1.25	TW

QUINAPRIL + HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension

Clinical criteria:

The treatment must not be for the initiation of anti-hypertensive therapy,

AND

The condition must be inadequately controlled with an ACE inhibitor; OR

The condition must be inadequately controlled with a thiazide diuretic.

Caution

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

8589C	quinapril 10 mg + hydrochlorothiazide	1	5	..	14.13	15.28	Accuretic 10/12.5mg	PF
NP	12.5 mg tablet, 30							
8590D	quinapril 20 mg + hydrochlorothiazide	1	5	..	15.34	16.49	Accuretic 20/12.5mg	PF
NP	12.5 mg tablet, 30							

ACE inhibitors and calcium channel blockers

LERCANIDIPINE + ENALAPRIL

Restricted benefit

Hypertension

Clinical criteria:

The treatment must not be for the initiation of anti-hypertensive therapy,

AND

The condition must be inadequately controlled with an ACE inhibitor; OR

The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

Caution

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

9144G	lercanidipine hydrochloride 10 mg + enalapril maleate 10 mg tablet, 28	1	5	..	14.13	15.28	Zan-Extra 10/10	GO
NP								
9145H	lercanidipine hydrochloride 10 mg + enalapril maleate 20 mg tablet, 28	1	5	..	15.30	16.45	Zan-Extra 10/20	GO
NP								

PERINDOPRIL + AMLODIPINE

Restricted benefit

Hypertension

Clinical criteria:

The treatment must not be for the initiation of anti-hypertensive therapy,

AND

The condition must be inadequately controlled with an ACE inhibitor; OR

The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

Restricted benefit

Stable coronary heart disease

Clinical criteria:

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
The treatment must not be for the initiation of therapy for coronary heart disease,								
AND								
The condition must be stabilised by treatment with perindopril and amlodipine at the same doses.								
Caution								
Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.								
9349C NP	perindopril arginine 10 mg + amlodipine 10 mg tablet, 30	1	5	..	40.60	37.70	^a Coveram 10/10	SE
9348B NP	perindopril arginine 10 mg + amlodipine 5 mg tablet, 30	1	5	..	33.28	34.43	^a Reaptan 10/10 ^a Coveram 10/5	RX SE
9347Y NP	perindopril arginine 5 mg + amlodipine 10 mg tablet, 30	1	5	..	34.79	35.94	^a Reaptan 10/5 ^a Coveram 5/10	RX SE
9346X NP	perindopril arginine 5 mg + amlodipine 5 mg tablet, 30	1	5	..	27.45	28.60	^a Reaptan 5/10 ^a Coveram 5/5	RX SE
							^a Reaptan 5/5	RX

RAMIPRIL + FELODIPINE

Restricted benefit

Hypertension

Clinical criteria:

The treatment must not be for the initiation of anti-hypertensive therapy,

AND

The condition must be inadequately controlled with an ACE inhibitor; OR

The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

Caution

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

2626F NP	ramipril 2.5 mg + felodipine 2.5 mg tablet: modified release, 30 tablets	1	5	..	13.10	14.25	Triasyn 2.5/2.5	SW
2629J NP	ramipril 5 mg + felodipine 5 mg tablet: modified release, 30 tablets	1	5	..	15.39	16.54	Triasyn 5.0/5.0	SW

TRANDOLAPRIL + VERAPAMIL

Restricted benefit

Hypertension

Clinical criteria:

The treatment must not be for the initiation of anti-hypertensive therapy,

AND

The condition must be inadequately controlled with an ACE inhibitor; OR

The condition must be inadequately controlled with verapamil.

Caution

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Caution

The myocardial depressant effects of verapamil hydrochloride and of beta-blocking drugs are additive.

9387C NP	trandolapril 2 mg + verapamil hydrochloride 180 mg tablet: modified release, 28 tablets	1	5	..	18.74	19.89	Tarka 2/180	GO
2857J NP	trandolapril 4 mg + verapamil hydrochloride 240 mg tablet: modified release, 28 tablets	1	5	..	25.72	26.87	Tarka 4/240	GO

ANGIOTENSIN II ANTAGONISTS, PLAIN

Angiotensin II antagonists, plain

CANDESARTAN

8297Q NP	candesartan cilexetil 16 mg tablet, 30	1	5	..	18.97	20.12	^a Adesan	AF
							^a APO-Candesartan	TX
							^a Auro-Candesartan 16	DO
							^a Candesartan AN	EA

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
8889W NP	candesartan cilexetil 32 mg tablet, 30	1	5	B1.59 ..	20.56 21.53	20.12 22.68	a Candesartan Aspen 16 QA
							a Candesartan-GA GN
							a Candesartan GH GQ
							a Candesartan RBX RA
							a Candesartan Sandoz SZ
							a Chem mart CH
							a Candesartan Pharmacor Candesartan 16 CR
							a Terry White Chemists Candesartan TW
							a Atacand AP
							a Adesan AF
							a APO-Candesartan TX
							a Auro-Candesartan 32 DO
							a Candesartan AN EA
							a Candesartan Aspen 32 QA
							a Candesartan-GA GN
							a Candesartan GH GQ
							a Candesartan RBX RA
							a Candesartan Sandoz SZ
							a Chem mart CH
8295N NP	candesartan cilexetil 4 mg tablet, 30	1	5	B1.57 ..	23.10 8.13	22.68 9.28	a Candesartan Pharmacor Candesartan 32 CR
							a Terry White Chemists Candesartan TW
							a Atacand AP
							a Adesan AF
							a APO-Candesartan TX
							a Auro-Candesartan 4 DO
							a Candesartan AN EA
							a Candesartan Aspen 4 QA
							a Candesartan-GA GN
							a Candesartan GH GQ
							a Candesartan RBX RA
							a Candesartan Sandoz SZ
							a Chem mart CH
							a Candesartan Pharmacor Candesartan 4 CR
							a Terry White Chemists Candesartan TW
							a Atacand AP
							a Adesan AF
							a APO-Candesartan TX
							a Auro-Candesartan 8 DO
8296P NP	candesartan cilexetil 8 mg tablet, 30	1	5	B1.59 ..	9.72 10.84	9.28 11.99	a Candesartan AN EA
							a Candesartan Aspen 8 QA
							a Candesartan-GA GN
							a Candesartan GH GQ
							a Candesartan RBX RA
							a Candesartan Sandoz SZ
							a Chem mart CH
							a Candesartan Pharmacor Candesartan 8 CR
							a Terry White Chemists Candesartan TW
							a Atacand AP
							a APO-Candesartan TX
							a Auro-Candesartan 8 DO
							a Candesartan AN EA
							a Candesartan Aspen 8 QA
							a Candesartan-GA GN
							a Candesartan GH GQ
							a Candesartan RBX RA
							a Candesartan Sandoz SZ
							a Chem mart CH
8397Y	EPROSARTAN eprosartan 400 mg tablet, 28	2	5	T3.50	*24.48	22.13	Teveten GO
							B1.58 12.42 11.99 a Atacand AP

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
NP 8447N NP	eprosartan 600 mg tablet, 28	1	5	3.50	28.07	25.72	Teveten	GO
EPROSARTAN								
<u>Authority required</u>								
Adverse effects occurring with all of the base-priced drugs								
<u>Authority required</u>								
Drug interactions occurring with all of the base-priced drugs								
<u>Authority required</u>								
Drug interactions expected to occur with all of the base-priced drugs								
<u>Authority required</u>								
Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance								
8951D NP	eprosartan 400 mg tablet, 28	2	5	..	*24.48	25.63	Teveten	GO
5491B NP	eprosartan 600 mg tablet, 28	1	5	..	28.07	29.22	Teveten	GO
IRBESARTAN								
8247C NP	irbesartan 150 mg tablet, 30	1	5	..	11.88	13.03	a Abisart	AF
							a APO-Irbesartan	TX
							a Avapro	AV
							a Chem mart Irbesartan	CH
							a Irbesartan Actavis 150	UA
							a Irbesartan AN	EA
							a Irbesartan-DRLA	RZ
							a Irbesartan-GA	GN
							a Irbesartan GH	GQ
							a Irbesartan RBX	RA
							a Irbesartan Sandoz	SZ
							a Irbesartan Winthrop	WA
							a Irprestan 150	ZP
							a Karbesat 150	QA
							a Karvea	SW
							a Terry White Chemists Irbesartan	TW
8248D NP	irbesartan 300 mg tablet, 30	1	5	..	16.98	18.13	a Abisart	AF
							a APO-Irbesartan	TX
							a Avapro	AV
							a Chem mart Irbesartan	CH
							a Irbesartan Actavis 300	UA
							a Irbesartan AN	EA
							a Irbesartan-DRLA	RZ
							a Irbesartan-GA	GN
							a Irbesartan GH	GQ
							a Irbesartan RBX	RA
							a Irbesartan Sandoz	SZ
							a Irbesartan Winthrop	WA
							a Irprestan 300	ZP
							a Karbesat 300	QA
							a Karvea	SW
							a Terry White Chemists Irbesartan	TW
8246B NP	irbesartan 75 mg tablet, 30	1	5	..	10.35	11.50	a Abisart	AF
							a APO-Irbesartan	TX
							a Avapro	AV
							a Chem mart Irbesartan	CH
							a Irbesartan Actavis 75	UA
							a Irbesartan AN	EA
							a Irbesartan-DRLA	RZ
							a Irbesartan-GA	GN

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							^a Irbesartan GH	GQ
							^a Irbesartan RBX	RA
							^a Irbesartan Sandoz	SZ
							^a Irbesartan Winthrop	WA
							^a Irprestan 75	ZP
							^a Karbesat 75	QA
							^a Karvea	SW
							^a Terry White Chemists Irbesartan	TW
	LOSARTAN							
5452Y NP	losartan potassium 25 mg tablet, 30	1	5	..	13.05	14.20	Cozavan	AF
8203R NP	losartan potassium 50 mg tablet, 30	2	5	..	*24.74	25.89	Cozavan	AF
	OLMESARTAN MEDOXOMIL							
2147B NP	olmesartan medoxomil 20 mg tablet, 30	1	5	^T 3.49	19.44	17.10	Olmotec	MK
2148C NP	olmesartan medoxomil 40 mg tablet, 30	1	5	^T 3.50	29.75	27.40	Olmotec	MK
	OLMESARTAN MEDOXOMIL							
	<u>Authority required</u>							
	Adverse effects occurring with all of the base-priced drugs							
	<u>Authority required</u>							
	Drug interactions occurring with all of the base-priced drugs							
	<u>Authority required</u>							
	Drug interactions expected to occur with all of the base-priced drugs							
	<u>Authority required</u>							
	Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance							
5492C NP	olmesartan medoxomil 20 mg tablet, 30	1	5	..	19.44	20.59	Olmotec	MK
5493D NP	olmesartan medoxomil 40 mg tablet, 30	1	5	..	29.75	30.90	Olmotec	MK
	TELMISARTAN							
8355R NP	telmisartan 40 mg tablet, 28	1	5	..	13.28	14.43	^a APO-Telmisartan	TX
							^a Chem mart Telmisartan	CH
							^a Micardis	BY
							^a Mizart	AF
							^a Pharmacor Telmisartan 40	CR
							^a Telmigen	GN
							^a Telmisartan AN	EA
							^a Telmisartan-DRLA	RZ
							^a Telmisartan GH	GQ
							^a Telmisartan RBX	RA
							^a Telmisartan Sandoz	SZ
							^a Teltartan	QA
							^a Terry White Chemists Telmisartan	TW
8356T NP	telmisartan 80 mg tablet, 28	1	5	..	25.65	26.80	^a APO-Telmisartan	TX
							^a Chem mart Telmisartan	CH
							^a Micardis	BY
							^a Mizart	AF
							^a Pharmacor Telmisartan 80	CR
							^a Telmigen	GN
							^a Telmisartan AN	EA
							^a Telmisartan-DRLA	RZ
							^a Telmisartan GH	GQ
							^a Telmisartan RBX	RA

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							a Telmisartan Sandoz	SZ
							a Teltartan	QA
							a Terry White Chemists Telmisartan	TW
VALSARTAN								
9370E NP	valsartan 160 mg tablet, 28	1	5	..	19.90	21.05	a APO-Valsartan	TX
							a Dilart	AF
							a Diovan	NV
9368C NP	valsartan 40 mg tablet, 28	1	..	..	13.79	14.94	a APO-Valsartan	TX
							a Dilart	AF
							a Diovan	NV
9369D NP	valsartan 80 mg tablet, 28	1	5	..	17.00	18.15	a APO-Valsartan	TX
							a Dilart	AF
							a Diovan	NV
VALSARTAN								
Note								
No applications for increased maximum quantities and/or repeats will be authorised for the 320 mg tablet.								
9371F NP	valsartan 320 mg tablet, 28	1	5	..	23.61	24.76	a APO-Valsartan	TX
							a Dilart	AF
							a Diovan	NV

ANGIOTENSIN II ANTAGONISTS, COMBINATIONS

Angiotensin II antagonists and diuretics

CANDESARTAN + HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension

Clinical criteria:

The treatment must not be for the initiation of anti-hypertensive therapy,

AND

The condition must be inadequately controlled with an angiotensin II antagonist; OR

The condition must be inadequately controlled with a thiazide diuretic.

8504N NP	candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30	1	5	..	22.84	23.99	a Adesan HCT 16/12.5	AF
							a APO-Candesartan HCTZ 16/12.5	TX
							a Candesartan/HCT Sandoz	SZ
							a Candesartan Combi Aspen 16/12.5	QA
							a Candesartan HCT GH 16/12.5	GQ
							a Candesartan HCTZ AN 16/12.5	EA
							a Candesartan HCTZ-GA 16/12.5	GN
							a Candesartan HCTZ RBX 16/12.5	RA
							a Chem mart Candesartan HCTZ 16/12.5	CH
							a Pharmacor Candesartan HCT 16/12.5	CR
							a Terry White Chemists Candesartan HCTZ 16/12.5	TW
				^b 2.00	24.84	23.99	a Atacand Plus 16/12.5	AP
9314F NP	candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet,	1	5	..	25.88	27.03	a Adesan HCT 32/12.5	AF

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	30						
							^a APO-Candesartan HCTZ 32/12.5 TX
							^a Candesartan/HCT Sandoz SZ
							^a Candesartan Combi Aspen 32/12.5 QA
							^a Candesartan HCT GH 32/12.5 GQ
							^a Candesartan HCTZ AN 32/12.5 EA
							^a Candesartan HCTZ-GA 32/12.5 GN
							^a Candesartan HCTZ RBX 32/12.5 RA
							^a Chem mart Candesartan HCTZ 32/12.5 CH
							^a Pharmacor Candesartan HCT 32/12.5 CR
							^a Terry White Chemists Candesartan HCTZ 32/12.5 TW
				^b 2.02	27.90	27.03	^a Atacand Plus 32/12.5 AP
9315G NP	candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30	1	5	..	27.33	28.48	^a Adesan HCT 32/25 AF
							^a APO-Candesartan HCTZ 32/25 TX
							^a Candesartan/HCT Sandoz SZ
							^a Candesartan Combi Aspen 32/25 QA
							^a Candesartan HCT GH 32/25 GQ
							^a Candesartan HCTZ AN 32/25 EA
							^a Candesartan HCTZ-GA 32/25 GN
							^a Candesartan HCTZ RBX 32/25 RA
							^a Chem mart Candesartan HCTZ 32/25 CH
							^a Pharmacor Candesartan HCT 32/25 CR
							^a Terry White Chemists Candesartan HCTZ 32/25 TW
				^b 2.00	29.33	28.48	^a Atacand Plus 32/25 AP

EPROSARTAN + HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension

Clinical criteria:

The treatment must not be for the initiation of anti-hypertensive therapy,

AND

The condition must be inadequately controlled with an angiotensin II antagonist; OR

The condition must be inadequately controlled with a thiazide diuretic.

8624X NP	eprosartan 600 mg + hydrochlorothiazide 12.5 mg tablet, 28	1	5	..	26.64	27.79	Teveten Plus 600/12.5 GO

IRBESARTAN + HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension

Clinical criteria:

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
The treatment must not be for the initiation of anti-hypertensive therapy, AND The condition must be inadequately controlled with an angiotensin II antagonist; OR The condition must be inadequately controlled with a thiazide diuretic.							
8404H NP	irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30	1	5	..	13.89	15.04	^a Abisart HCT 150/12.5 AF ^a APO-Irbesartan HCTZ TX ^a Avapro HCT 150/12.5 AV ^a Chem mart Irbesartan HCTZ CH ^a Irbesartan/HCT Sandoz SZ ^a Irbesartan/HCTZ RBX RA ^a 150/12.5 ^a Irbesartan HCT Actavis UA ^a 150/12.5 ^a Irbesartan HCT GH GQ ^a 150/12.5 ^a Irbesartan HCT WA ^a Winthrop 150/12.5 ^a Irbesartan HCTZ AN EA ^a 150/12.5 ^a Irbesartan HCTZ-GA GN ^a 150/12.5 ^a Karvezide 150/12.5 SW ^a KSART HCT 150/12.5 QA ^a Terry White Chemists Irbesartan HCTZ TW
8405J NP	irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30	1	5	..	19.86	21.01	^a Abisart HCT 300/12.5 AF ^a APO-Irbesartan HCTZ TX ^a Avapro HCT 300/12.5 AV ^a Chem mart Irbesartan HCTZ CH ^a Irbesartan/HCT Sandoz SZ ^a Irbesartan/HCTZ RBX RA ^a 300/12.5 ^a Irbesartan HCT Actavis UA ^a 300/12.5 ^a Irbesartan HCT GH GQ ^a 300/12.5 ^a Irbesartan HCT WA ^a Winthrop 300/12.5 ^a Irbesartan HCTZ AN EA ^a 300/12.5 ^a Irbesartan HCTZ-GA GN ^a 300/12.5 ^a Karvezide 300/12.5 SW ^a KSART HCT 300/12.5 QA ^a Terry White Chemists Irbesartan HCTZ TW
2136K NP	irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30	1	5	..	21.02	22.17	^a Abisart HCT 300/25 AF ^a APO-Irbesartan HCTZ TX ^a Avapro HCT 300/25 AV ^a Chem mart Irbesartan HCTZ CH ^a Irbesartan/HCT Sandoz SZ ^a Irbesartan/HCTZ RBX RA ^a 300/25 ^a Irbesartan HCT Actavis UA ^a 300/25 ^a Irbesartan HCT GH GQ ^a 300/25 ^a Irbesartan HCT WA ^a Winthrop 300/25

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							a Irbesartan HCTZ AN 300/25	EA
							a Irbesartan HCTZ-GA 300/25	GN
							a Karvezide 300/25	SW
							a KSART HCT 300/25	QA
							a Terry White Chemists Irbesartan HCTZ	TW
OLMESARTAN MEDOXOMIL + HYDROCHLOROTHIAZIDE								
<u>Restricted benefit</u>								
Hypertension								
Clinical criteria:								
The treatment must not be for the initiation of anti-hypertensive therapy,								
AND								
The condition must be inadequately controlled with an angiotensin II antagonist; OR								
The condition must be inadequately controlled with a thiazide diuretic.								
2161R NP	olmesartan medoxomil 20 mg + hydrochlorothiazide 12.5 mg tablet, 30	1	5	..	18.16	19.31	Olmotec Plus	MK
2166B NP	olmesartan medoxomil 40 mg + hydrochlorothiazide 12.5 mg tablet, 30	1	5	..	28.46	29.61	Olmotec Plus	MK
2170F NP	olmesartan medoxomil 40 mg + hydrochlorothiazide 25 mg tablet, 30	1	5	..	30.70	31.85	Olmotec Plus	MK
TELMISARTAN + HYDROCHLOROTHIAZIDE								
<u>Restricted benefit</u>								
Hypertension								
Clinical criteria:								
The treatment must not be for the initiation of anti-hypertensive therapy,								
AND								
The condition must be inadequately controlled with an angiotensin II antagonist; OR								
The condition must be inadequately controlled with a thiazide diuretic.								
8622T NP	telmisartan 40 mg + hydrochlorothiazide 12.5 mg tablet, 28	1	5	..	15.02	16.17	a APO-Telmisartan HCTZ 40/12.5	TX
							a Chem mart Telmisartan HCTZ 40/12.5	CH
							a Micardis Plus 40/12.5 mg	BY
							a Mizart HCT 40/12.5 mg	AF
							a Pritor Plus 40/12.5 mg	FI
							a Telmigen HCT 40/12.5	GN
							a Telmisartan/HCT Sandoz	SZ
							a Telmisartan HCT GH 40/12.5	GQ
							a Telmisartan HCTZ AN 40/12.5	EA
							a Teltartan HCT 40/12.5	QA
							a Terry White Chemists Telmisartan HCTZ 40/12.5	TW
8623W NP	telmisartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28	1	5	..	27.40	28.55	a APO-Telmisartan HCTZ 80/12.5	TX
							a Chem mart Telmisartan HCTZ 80/12.5	CH
							a Micardis Plus 80/12.5 mg	BY
							a Mizart HCT 80/12.5 mg	AF
							a Pritor Plus 80/12.5 mg	FI
							a Telmigen HCT 80/12.5	GN

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							^a Telmisartan/HCT Sandoz	SZ
							^a Telmisartan HCT GH 80/12.5	GQ
							^a Telmisartan HCTZ AN 80/12.5	EA
							^a Teltartan HCT 80/12.5	QA
							^a Terry White Chemists Telmisartan HCTZ 80/12.5	TW
9381R NP	telmisartan 80 mg + hydrochlorothiazide 25 mg tablet, 28	1	5	..	29.14	30.29	^a APO-Telmisartan HCTZ 80/25	TX
							^a Chem mart Telmisartan HCTZ 80/25	CH
							^a Micardis Plus 80/25 mg	BY
							^a Mizart HCT 80/25 mg	AF
							^a Pritor Plus 80/25 mg	FI
							^a Telmigen HCT 80/25	GN
							^a Telmisartan/HCT Sandoz	SZ
							^a Telmisartan HCT GH 80/25	GQ
							^a Telmisartan HCTZ AN 80/25	EA
							^a Teltartan HCT 80/25	QA
							^a Terry White Chemists Telmisartan HCTZ 80/25	TW

VALSARTAN + HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension

Clinical criteria:

The treatment must not be for the initiation of anti-hypertensive therapy,

AND

The condition must be inadequately controlled with an angiotensin II antagonist; OR

The condition must be inadequately controlled with a thiazide diuretic.

9373H NP	valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28	1	5	..	21.65	22.80	^a APO-Valsartan HCTZ 160/12.5	TX
							^a Co-Diovan 160/12.5	NV
							^a Dilart HCT 160/12.5	AF
9374J NP	valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28	1	5	..	23.39	24.54	^a Co-Diovan 160/25	NV
							^a Dilart HCT 160/25	AF
9372G NP	valsartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28	1	5	..	18.74	19.89	^a Co-Diovan 80/12.5	NV
							^a Dilart HCT 80/12.5	AF

VALSARTAN + HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension

Clinical criteria:

The treatment must not be for the initiation of anti-hypertensive therapy,

AND

The condition must be inadequately controlled with an angiotensin II antagonist; OR

The condition must be inadequately controlled with a thiazide diuretic.

Note

No applications for increased maximum quantities and/or repeats will be authorised for the tablets containing 320 mg valsartan.

9481B NP	valsartan 320 mg + hydrochlorothiazide 12.5 mg tablet, 28	1	5	..	25.36	26.51	^a APO-Valsartan HCTZ 320/12.5	TX
							^a Co-Diovan 320/12.5	NV
							^a Dilart HCT 320/12.5	AF
9482C	valsartan 320 mg + hydrochlorothiazide	1	5	..	27.10	28.25	^a APO-Valsartan HCTZ	TX

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
NP	25 mg tablet, 28						320/25	
							a Co-Diovan 320/25	NV
							a Dilart HCT 320/25	AF

Angiotensin II antagonists and calcium channel blockers

AMLODIPINE + VALSARTAN

Restricted benefit

Hypertension

Clinical criteria:

The treatment must not be for the initiation of anti-hypertensive therapy,

AND

The condition must be inadequately controlled with an angiotensin II antagonist; OR

The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

9377M NP	amlodipine 10 mg + valsartan 160 mg tablet, 28	1	5	..	28.98	30.13	Exforge 10/160	NV
5460J NP	amlodipine 10 mg + valsartan 320 mg tablet, 28	1	5	..	32.81	33.96	Exforge 10/320	NV
9376L NP	amlodipine 5 mg + valsartan 160 mg tablet, 28	1	5	..	25.44	26.59	Exforge 5/160	NV
5459H NP	amlodipine 5 mg + valsartan 320 mg tablet, 28	1	5	..	29.28	30.43	Exforge 5/320	NV
9375K NP	amlodipine 5 mg + valsartan 80 mg tablet, 28	1	5	..	22.37	23.52	a Exforge 5/80	NV
							a Valsartan/Amlodipine Sandoz 80/5	NM

OLMESARTAN MEDOXOMIL + AMLODIPINE

Restricted benefit

Hypertension

Clinical criteria:

The treatment must not be for the initiation of anti-hypertensive therapy,

AND

The condition must be inadequately controlled with an angiotensin II antagonist; OR

The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

5292M NP	olmesartan medoxomil 20 mg + amlodipine 5 mg tablet, 30	1	5	..	17.44	18.59	Sevikar 20/5	MK
5294P NP	olmesartan medoxomil 40 mg + amlodipine 10 mg tablet, 30	1	5	..	28.86	30.01	Sevikar 40/10	MK
5293N NP	olmesartan medoxomil 40 mg + amlodipine 5 mg tablet, 30	1	5	..	27.75	28.90	Sevikar 40/5	MK

TELMISARTAN + AMLODIPINE

Restricted benefit

Hypertension

Clinical criteria:

The treatment must not be for the initiation of anti-hypertensive therapy,

AND

The condition must be inadequately controlled with an angiotensin II antagonist; OR

The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

8979N NP	telmisartan 40 mg + amlodipine 10 mg tablet, 28	1	5	..	16.66	17.81	a Pritor/Amlodipine	FI
							a Twynsta	BY
8978M NP	telmisartan 40 mg + amlodipine 5 mg tablet, 28	1	5	..	15.21	16.36	a Pritor/Amlodipine	FI
							a Twynsta	BY
8981Q NP	telmisartan 80 mg + amlodipine 10 mg tablet, 28	1	5	..	29.05	30.20	a Pritor/Amlodipine	FI
							a Twynsta	BY
8980P NP	telmisartan 80 mg + amlodipine 5 mg tablet, 28	1	5	..	27.60	28.75	a Pritor/Amlodipine	FI
							a Twynsta	BY

Angiotensin II antagonists, other combinations

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
AMLODIPINE + VALSARTAN + HYDROCHLOROTHIAZIDE								
<u>Restricted benefit</u>								
Hypertension								
Clinical criteria:								
The treatment must not be for the initiation of anti-hypertensive therapy,								
AND								
The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.								
5287G NP	amlodipine 10 mg + valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28	1	5	..	30.71	31.86	Exforge HCT 10/160/12.5	NV
5288H NP	amlodipine 10 mg + valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28	1	5	..	32.45	33.60	Exforge HCT 10/160/25	NV
5289J NP	amlodipine 10 mg + valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28	1	5	..	36.32	37.47	Exforge HCT 10/320/25	NV
5285E NP	amlodipine 5 mg + valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28	1	5	..	27.17	28.32	^a Exforge HCT 5/160/12.5	NV
							^a Valsartan/Amlodipine/HCT Sandoz 160/5/12.5	NM
5286F NP	amlodipine 5 mg + valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28	1	5	..	28.92	30.07	Exforge HCT 5/160/25	NV
OLMESARTAN + AMLODIPINE + HYDROCHLOROTHIAZIDE								
<u>Restricted benefit</u>								
Hypertension								
Clinical criteria:								
The treatment must not be for the initiation of anti-hypertensive therapy,								
AND								
The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.								
10005N NP	olmesartan medoxomil 20 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30	1	5	..	19.67	20.82	Sevikar HCT 20/5/12.5	MK
2836G NP	olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 12.5 mg tablet, 30	1	5	..	31.09	32.24	Sevikar HCT 40/10/12.5	MK
2953K NP	olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 25 mg tablet, 30	1	5	..	33.33	34.48	Sevikar HCT 40/10/25	MK
2880N NP	olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30	1	5	..	29.97	31.12	Sevikar HCT 40/5/12.5	MK
2864R NP	olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 25 mg tablet, 30	1	5	..	32.20	33.35	Sevikar HCT 40/5/25	MK

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

GENERAL STATEMENT FOR LIPID-LOWERING DRUGS PRESCRIBED AS PHARMACEUTICAL BENEFITS

Use the following criteria to determine patient eligibility for subsidisation under the PBS for the following drugs:

- atorvastatin calcium
- fluvastatin sodium
- pravastatin sodium
- rosuvastatin calcium
- simvastatin
- fenofibrate
- gemfibrozil

By writing a PBS prescription, the prescriber is certifying the patient satisfies the qualifying criteria set out below and the use is in accordance with the registered indications which differ between agents in this class - refer to the current Product Information for details. Note also that patients already established on a particular lipid-lowering drug, where use satisfies the PBS qualifying criteria, but is outside the registered indications for that drug, are not required to switch to another drug in the class to retain PBS eligibility.

Patients in very high risk categories (see below) may commence drug therapy with statins or fibrates immediately (ie simultaneously with an appropriate diet). For all other patients, dietary therapy should be trialled prior to initiation of drug therapy.

Dietary therapy should be continued concurrently with pharmacological therapy and should be reviewed on at least an annual basis.

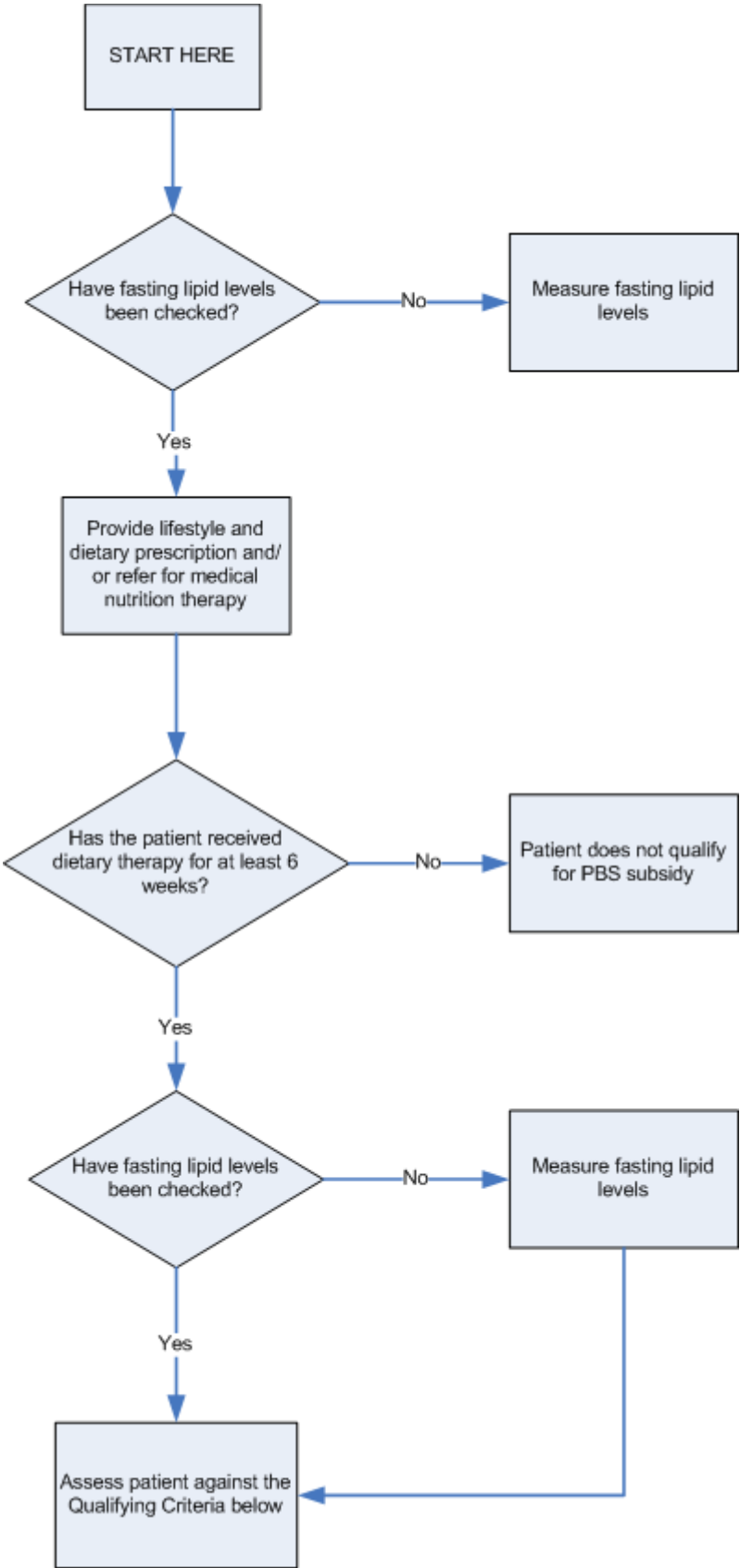
Patients identified as being in one of the following very high risk categories may commence drug therapy with statins or fibrates at any cholesterol level:

- coronary heart disease which has become symptomatic
- cerebrovascular disease which has become symptomatic
- peripheral vascular disease which has become symptomatic
- diabetes mellitus with microalbuminuria (defined as urinary albumin excretion rate of >20mcg/min or urinary albumin to creatinine ratio of > 2.5 for males, > 3.5 for females)
- diabetes mellitus in Aboriginal or Torres Strait Islander patients
- diabetes mellitus in patients aged 60 years or more
- family history of coronary heart disease which has become symptomatic before the age of 55 years in two or more first degree relatives
- family history of coronary heart disease which has become symptomatic before the age of 45 years in one or more first degree relatives

If your patient is not identified as being in any of the above very high risk categories, then use the flow-chart and table below to determine whether your patient satisfies the following criteria for subsidisation under the PBS. Document how the patient meets each of these steps in the patient record. Lipid levels must be measured at an accredited laboratory.

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer



CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

POST-DIETARY QUALIFYING CRITERIA

Dietary therapy should be continued concurrently with pharmacological therapy and should be reviewed on at least an annual basis.

PATIENT CATEGORY	LIPID LEVELS FOR PBS SUBSIDY
Patients with diabetes mellitus not otherwise included	total cholesterol > 5.5 mmol/L
Aboriginal or Torres Strait Islander patients Patients with hypertension	total cholesterol > 6.5 mmol/L or total cholesterol > 5.5 mmol/L and HDL cholesterol < 1 mmol/L
Patients with HDL cholesterol < 1 mmol/L	total cholesterol > 6.5 mmol/L
Patients with familial hypercholesterolaemia identified by: - DNA mutation; or - tendon xanthomas in the patient or their first or second degree relative Patients with: - family history of coronary heart disease which has become symptomatic before the age of 60 years in one or more first degree relatives; or - family history of coronary heart disease which has become symptomatic before the age of 50 years in one or more second degree relatives	If aged 18 years or less at treatment initiation: LDL cholesterol > 4 mmol/L If aged more than 18 years at treatment initiation: LDL cholesterol > 5 mmol/L or total cholesterol > 6.5 mmol/L or total cholesterol > 5.5 mmol/L and HDL cholesterol < 1 mmol/L
Patients not eligible under the above: - men aged 35 to 75 years - post-menopausal women aged up to 75 years	total cholesterol > 7.5 mmol/L or triglyceride > 4 mmol/L
Patients not otherwise included	total cholesterol > 9 mmol/L or triglyceride > 8 mmol/L

LIPID MODIFYING AGENTS

LIPID MODIFYING AGENTS, PLAIN *HMG CoA reductase inhibitors*

ATORVASTATIN

Restricted benefit

For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs

8213G NP	atorvastatin 10 mg tablet, 30	1	5	..	11.41	12.56	a	APO-Atorvastatin	TX
							a	Atorvachol	GN
							a	Atorvastatin AN	EA
							a	Atorvastatin GH	GQ
							a	Atorvastatin Pfizer	FZ
							a	Atorvastatin Sandoz	SZ
							a	Atorvastatin SCP 10	RZ
							a	Atorvastatin SZ	HX
							a	Blooms the Chemist Atorvastatin	IB
							a	Chem mart Atorvastatin	CH
							a	Lipitor	PF
							a	Lorstat 10	AF
							a	Terry White Chemists Atorvastatin	TW

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
8214H NP	atorvastatin 20 mg tablet, 30	1	5	..	13.63	14.78	a Torvastat 10	QA
							a Trovas	RA
							a APO-Atorvastatin	TX
							a Atorvachol	GN
							a Atorvastatin AN	EA
							a Atorvastatin GH	GQ
							a Atorvastatin Pfizer	FZ
							a Atorvastatin Sandoz	SZ
							a Atorvastatin SCP 20	RZ
							a Atorvastatin SZ	HX
							a Blooms the Chemist Atorvastatin	IB
							a Chem mart Atorvastatin	CH
							a Lipitor	PF
							a Lorstat 20	AF
8215J NP	atorvastatin 40 mg tablet, 30	1	5	..	16.43	17.58	a Terry White Chemists Atorvastatin	TW
							a Torvastat 20	QA
							a Trovas	RA
							a APO-Atorvastatin	TX
							a Atorvachol	GN
							a Atorvastatin AN	EA
							a Atorvastatin GH	GQ
							a Atorvastatin Pfizer	FZ
							a Atorvastatin Sandoz	SZ
							a Atorvastatin SCP 40	RZ
							a Atorvastatin SZ	HX
							a Blooms the Chemist Atorvastatin	IB
							a Chem mart Atorvastatin	CH
							a Lipitor	PF
8521L NP	atorvastatin 80 mg tablet, 30	1	5	..	20.58	21.73	a Lorstat 40	AF
							a Terry White Chemists Atorvastatin	TW
							a Torvastat 40	QA
							a Trovas	RA
							a APO-Atorvastatin	TX
							a Atorvachol	GN
							a Atorvastatin AN	EA
							a Atorvastatin GH	GQ
							a Atorvastatin Pfizer	FZ
							a Atorvastatin Sandoz	SZ
							a Atorvastatin SCP 80	RZ
							a Atorvastatin SZ	HX
							a Blooms the Chemist Atorvastatin	IB
							a Chem mart Atorvastatin	CH
							a Lipitor	PF
							a Lorstat 80	AF
							a Terry White Chemists Atorvastatin	TW
							a Torvastat 80	QA
							a Trovas	RA

ATORVASTATIN

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

Note

No applications for increased maximum quantities and/or repeats will be authorised.

9230T	atorvastatin 10 mg tablet, 30	1	11	..	11.41	12.56	a APO-Atorvastatin	TX

CARDIOVASCULAR SYSTEM

[illegible]

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							a Chem mart Atorvastatin	CH
							a Lipitor	PF
							a Lorstat 80	AF
							a Terry White Chemists Atorvastatin	TW
							a Torvastat 80	QA
							a Trovas	RA
FLUVASTATIN								
<u>Restricted benefit</u>								
For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs								
8023G NP	fluvastatin 20 mg capsule, 28	1	5	..	25.80	26.95	a Lescol	NV
				^B 3.09	28.89	26.95	a Vastin	NM
8024H NP	fluvastatin 40 mg capsule, 28	1	5	..	30.11	31.26	a Lescol	NV
				^B 3.38	33.49	31.26	a Vastin	NM
2863Q NP	fluvastatin 80 mg tablet: modified release, 28 tablets	1	5	..	45.76	37.70	Lescol XL	NV
FLUVASTATIN								
<u>Restricted benefit</u>								
For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements								
<u>Note</u>								
No applications for increased maximum quantities and/or repeats will be authorised.								
9234B	fluvastatin 20 mg capsule, 28	1	11	..	25.80	26.95	a Lescol	NV
				^B 3.09	28.89	26.95	a Vastin	NM
9235C	fluvastatin 40 mg capsule, 28	1	11	..	30.11	31.26	a Lescol	NV
				^B 3.38	33.49	31.26	a Vastin	NM
9236D	fluvastatin 80 mg tablet: modified release, 28 tablets	1	11	..	45.76	37.70	Lescol XL	NV
PRAVASTATIN								
<u>Restricted benefit</u>								
For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs								
2833D NP	pravastatin sodium 10 mg tablet, 30	1	5	..	9.23	10.38	a APO-Pravastatin	TX
							a Auro-Pravastatin 10	DO
							a Chem mart Pravastatin	CH
							a Cholstat 10	AF
							a Lipostat 10	QA
							a Pharmacor Pravastat 10	CR
							a Pravastatin Actavis 10	UA
							a Pravastatin AN	EA
							a Pravastatin-GA 10	GN
							a Pravastatin generichealth	GQ
							a Pravastatin Sandoz	SZ
							a Terry White Chemists Pravastatin	TW
				^B 1.38	10.61	10.38	a Pravachol	FM
2834E NP	pravastatin sodium 20 mg tablet, 30	1	5	..	10.68	11.83	a APO-Pravastatin	TX
							a Auro-Pravastatin 20	DO
							a Chem mart Pravastatin	CH
							a Cholstat 20	AF
							a Cholvastin	RA
							a Lipostat 20	QA
							a Pharmacor Pravastat 20	CR
							a Pravastatin Actavis 20	UA

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
8197K NP	pravastatin sodium 40 mg tablet, 30	1	5	^B 1.37 ..	12.05 12.86	11.83 14.01	a Pravastatin AN	EA
							a Pravastatin-GA 20	GN
							a Pravastatin generichealth	GQ
							a Pravastatin Sandoz	SZ
							a Terry White Chemists Pravastatin	TW
							a Pravachol	FM
							a APO-Pravastatin	TX
							a Auro-Pravastatin 40	DO
							a Chem mart Pravastatin	CH
							a Cholstat 40	AF
							a Cholvastin	RA
							a Lipostat 40	QA
							a Pharmacor Pravastat 40	CR
							a Pravastatin Actavis 40	UA
							a Pravastatin AN	EA
							a Pravastatin-GA 40	GN
							a Pravastatin generichealth	GQ
8829Q NP	pravastatin sodium 80 mg tablet, 30	1	5	^B 1.46 ..	14.32 16.13	14.01 17.28	a Pravastatin Sandoz	SZ
							a Terry White Chemists Pravastatin	TW
							a Pravachol	FM
							a APO-Pravastatin	TX
							a Auro-Pravastatin 80	DO
							a Chem mart Pravastatin	CH
							a Lipostat 80	QA
							a Pravastatin AN	EA
							a Pravastatin-GA 80	GN
							a Pravastatin generichealth	GQ
							a Pravastatin Sandoz	SZ
							a Terry White Chemists Pravastatin	TW
							^B 1.46	
							17.59	
							17.28	
							a Pravachol	FM
9237E	pravastatin sodium 10 mg tablet, 30	1	11	..	9.23	10.38	a APO-Pravastatin	TX
							a Auro-Pravastatin 10	DO
							a Chem mart Pravastatin	CH
							a Cholstat 10	AF
							a Lipostat 10	QA
							a Pharmacor Pravastat 10	CR
							a Pravastatin Actavis 10	UA
							a Pravastatin AN	EA
							a Pravastatin-GA 10	GN
							a Pravastatin generichealth	GQ
							a Pravastatin Sandoz	SZ
							a Terry White Chemists Pravastatin	TW
							^B 1.38	
							10.61	
							10.38	
							a Pravachol	FM
9238F	pravastatin sodium 20 mg tablet, 30	1	11	..	10.68	11.83	a APO-Pravastatin	TX
							a Auro-Pravastatin 20	DO

PRAVASTATIN

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

Note

No applications for increased maximum quantities and/or repeats will be authorised.

2584B	rosuvastatin 10 mg tablet, 30	1	11	..	26.68	27.83	^a	AP0-Rosuvastatin	TX
							^a	Blooms the Chemist Rosuvastatin	IB
							^a	Cavstat	AF
							^a	Chem mart Rosuvastatin	CH
							^a	Crestor	AP

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
2609H	rosuvastatin 20 mg tablet, 30	1	11	..	35.11	36.26	a Crosuva 10	ZP
							a Rosuvastatin Actavis 10	GN
							a Rosuvastatin-DRLA	RI
							a Rosuvastatin GH	GQ
							a Terry White Chemists Rosuvastatin	TW
							a APO-Rosuvastatin	TX
							a Blooms the Chemist Rosuvastatin	IB
							a Cavstat	AF
							a Chem mart Rosuvastatin	CH
							a Crestor	AP
2636R	rosuvastatin 40 mg tablet, 30	1	11	..	46.43	37.70	a Crosuva 20	ZP
							a Rosuvastatin Actavis 20	GN
							a Rosuvastatin-DRLA	RI
							a Rosuvastatin GH	GQ
							a Terry White Chemists Rosuvastatin	TW
							a APO-Rosuvastatin	TX
							a Blooms the Chemist Rosuvastatin	IB
							a Cavstat	AF
							a Chem mart Rosuvastatin	CH
							a Crestor	AP
2590H	rosuvastatin 5 mg tablet, 30	1	11	..	20.32	21.47	a Crosuva 40	ZP
							a Rosuvastatin Actavis 40	GN
							a Rosuvastatin-DRLA	RI
							a Rosuvastatin GH	GQ
							a Terry White Chemists Rosuvastatin	TW
							a APO-Rosuvastatin	TX
							a Blooms the Chemist Rosuvastatin	IB
							a Cavstat	AF
							a Chem mart Rosuvastatin	CH
							a Crestor	AP
2628H NP	rosuvastatin 10 mg tablet, 30	1	5	..	26.68	27.83	a Crosuva 5	ZP
							a Rosuvastatin Actavis 5	GN
							a Rosuvastatin-DRLA	RI
							a Rosuvastatin GH	GQ
							a Terry White Chemists Rosuvastatin	TW
							a APO-Rosuvastatin	TX
							a Blooms the Chemist Rosuvastatin	IB
							a Cavstat	AF
							a Chem mart Rosuvastatin	CH
							a Crestor	AP
							a Crosuva 10	ZP
							a Rosuvastatin Actavis 10	GN
							a Rosuvastatin-DRLA	RI
							a Rosuvastatin GH	GQ
							a Terry White Chemists Rosuvastatin	TW

ROSUVASTATIN

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
2574L NP	rosuvastatin 20 mg tablet, 30	1	5	..	35.11	36.26	^a APO-Rosuvastatin	TX
							^a Blooms the Chemist Rosuvastatin	IB
							^a Cavstat	AF
							^a Chem mart Rosuvastatin	CH
							^a Crestor	AP
							^a Crosuva 20	ZP
							^a Rosuvastatin Actavis 20	GN
							^a Rosuvastatin-DRLA	RI
							^a Rosuvastatin GH	GQ
							^a Terry White Chemists Rosuvastatin	TW
2594M NP	rosuvastatin 40 mg tablet, 30	1	5	..	46.43	37.70	^a APO-Rosuvastatin	TX
							^a Blooms the Chemist Rosuvastatin	IB
							^a Cavstat	AF
							^a Chem mart Rosuvastatin	CH
							^a Crestor	AP
							^a Crosuva 40	ZP
							^a Rosuvastatin Actavis 40	GN
							^a Rosuvastatin-DRLA	RI
							^a Rosuvastatin GH	GQ
							^a Terry White Chemists Rosuvastatin	TW
2606E NP	rosuvastatin 5 mg tablet, 30	1	5	..	20.32	21.47	^a APO-Rosuvastatin	TX
							^a Blooms the Chemist Rosuvastatin	IB
							^a Cavstat	AF
							^a Chem mart Rosuvastatin	CH
							^a Crestor	AP
							^a Crosuva 5	ZP
							^a Rosuvastatin Actavis 5	GN
							^a Rosuvastatin-DRLA	RI
							^a Rosuvastatin GH	GQ
							^a Terry White Chemists Rosuvastatin	TW

ROSUVASTATIN

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

Clinical criteria:

Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements,

AND

The treatment must not be prescribed for hypercholesterolaemia if the patient has heterozygous familial hypercholesterolaemia.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

3403D	rosuvastatin 10 mg tablet, 30	1	11	..	26.68	27.83	^a APO-Rosuvastatin	TX
							^a Blooms the Chemist Rosuvastatin	IB
							^a Cavstat	AF
							^a Chem mart Rosuvastatin	CH
							^a Crestor	AP
							^a Crosuva 10	ZP

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
3404E	rosuvastatin 20 mg tablet, 30	1	11	..	35.11	36.26	a Rostor 10	DO
							a Rosuvastatin Actavis 10	GN
							a Rosuvastatin AN	EA
							a Rosuvastatin-DRLA	RI
							a Rosuvastatin GH	GQ
							a Rosuvastatin RBX	RA
							a Rosuvastatin Sandoz	SZ
							a Terry White Chemists Rosuvastatin	TW
							a APO-Rosuvastatin	TX
							a Blooms the Chemist Rosuvastatin	IB
							a Cavstat	AF
							a Chem mart Rosuvastatin	CH
							a Crestor	AP
							a Crosva 20	ZP
3405F	rosuvastatin 40 mg tablet, 30	1	11	..	46.43	37.70	a Rostor 20	DO
							a Rosuvastatin Actavis 20	GN
							a Rosuvastatin AN	EA
							a Rosuvastatin-DRLA	RI
							a Rosuvastatin GH	GQ
							a Rosuvastatin RBX	RA
							a Rosuvastatin Sandoz	SZ
							a Terry White Chemists Rosuvastatin	TW
							a APO-Rosuvastatin	TX
							a Blooms the Chemist Rosuvastatin	IB
							a Cavstat	AF
							a Chem mart Rosuvastatin	CH
							a Crestor	AP
							a Crosva 40	ZP
3402C	rosuvastatin 5 mg tablet, 30	1	11	..	20.32	21.47	a Rostor 40	DO
							a Rosuvastatin Actavis 40	GN
							a Rosuvastatin AN	EA
							a Rosuvastatin-DRLA	RI
							a Rosuvastatin GH	GQ
							a Rosuvastatin RBX	RA
							a Rosuvastatin Sandoz	SZ
							a Terry White Chemists Rosuvastatin	TW
							a APO-Rosuvastatin	TX
							a Blooms the Chemist Rosuvastatin	IB
							a Cavstat	AF
							a Chem mart Rosuvastatin	CH
							a Crestor	AP
							a Crosva 5	ZP
							a Rostor 5	DO
							a Rosuvastatin Actavis 5	GN
							a Rosuvastatin AN	EA
							a Rosuvastatin-DRLA	RI
							a Rosuvastatin GH	GQ
							a Rosuvastatin RBX	RA
							a Rosuvastatin Sandoz	SZ
							a Terry White Chemists Rosuvastatin	TW

ROSUVASTATIN

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
<u>Restricted benefit</u>							
For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs							
Clinical criteria:							
The treatment must not be prescribed for hypercholesterolaemia if the patient has heterozygous familial hypercholesterolaemia.							
9043Y NP	rosuvastatin 10 mg tablet, 30	1	5	..	26.68	27.83	^a APO-Rosuvastatin TX
							^a Blooms the Chemist Rosuvastatin IB
							^a Cavstat AF
							^a Chem mart Rosuvastatin CH
							^a Crestor AP
							^a Croсуva 10 ZP
							^a Rostor 10 DO
							^a Rosuvastatin Actavis 10 GN
							^a Rosuvastatin AN EA
							^a Rosuvastatin-DRLA RI
							^a Rosuvastatin GH GQ
							^a Rosuvastatin RBX RA
							^a Rosuvastatin Sandoz SZ
							^a Terry White Chemists Rosuvastatin TW
							^a APO-Rosuvastatin TX
9044B NP	rosuvastatin 20 mg tablet, 30	1	5	..	35.11	36.26	^a Blooms the Chemist Rosuvastatin IB
							^a Cavstat AF
							^a Chem mart Rosuvastatin CH
							^a Crestor AP
							^a Croсуva 20 ZP
							^a Rostor 20 DO
							^a Rosuvastatin Actavis 20 GN
							^a Rosuvastatin AN EA
							^a Rosuvastatin-DRLA RI
							^a Rosuvastatin GH GQ
							^a Rosuvastatin RBX RA
							^a Rosuvastatin Sandoz SZ
							^a Terry White Chemists Rosuvastatin TW
							^a APO-Rosuvastatin TX
							^a Blooms the Chemist Rosuvastatin IB
							^a Cavstat AF
9045C NP	rosuvastatin 40 mg tablet, 30	1	5	..	46.43	37.70	^a Chem mart Rosuvastatin CH
							^a Crestor AP
							^a Croсуva 40 ZP
							^a Rostor 40 DO
							^a Rosuvastatin Actavis 40 GN
							^a Rosuvastatin AN EA
							^a Rosuvastatin-DRLA RI
							^a Rosuvastatin GH GQ
							^a Rosuvastatin RBX RA
							^a Rosuvastatin Sandoz SZ
							^a Terry White Chemists Rosuvastatin TW
							^a APO-Rosuvastatin TX
							^a Blooms the Chemist Rosuvastatin IB
							^a Cavstat AF
							^a Chem mart Rosuvastatin CH
							^a Crestor AP
9042X NP	rosuvastatin 5 mg tablet, 30	1	5	..	20.32	21.47	^a APO-Rosuvastatin TX
							^a Blooms the Chemist Rosuvastatin IB
							^a Cavstat AF
							^a Chem mart Rosuvastatin CH

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							a Crestor	AP
							a Crosva 5	ZP
							a Rostor 5	DO
							a Rosuvastatin Actavis 5	GN
							a Rosuvastatin AN	EA
							a Rosuvastatin-DRLA	RI
							a Rosuvastatin GH	GQ
							a Rosuvastatin RBX	RA
							a Rosuvastatin Sandoz	SZ
							a Terry White Chemists Rosuvastatin	TW
	SIMVASTATIN							
	<u>Restricted benefit</u>							
	For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs							
2011W NP	simvastatin 10 mg tablet, 30	1	5	..	8.95	10.10	a APO-Simvastatin	TX
							a Auro-Simvastatin 10	DO
							a Chem mart Simvastatin	CH
							a GenRx Simvastatin	GX
							a Ransim	RA
							a Simvacor 10	CR
							a Simvar 10	QA
							a Simvastatin AN	EA
							a Simvastatin-DP	UA
							a Simvastatin-DRLA	RZ
							a Simvastatin-GA 10	GN
							a Simvastatin generichealth	GQ
							a Simvastatin Sandoz	SZ
							a Terry White Chemists Simvastatin	TW
				^B 3.33	12.28	10.10	a Zimstat	AF
							a Lipex 10	FR
							a Zocor	MK
2012X NP	simvastatin 20 mg tablet, 30	1	5	..	9.92	11.07	a APO-Simvastatin	TX
							a Auro-Simvastatin 20	DO
							a Chem mart Simvastatin	CH
							a Ransim	RA
							a Simvacor 20	CR
							a Simvar 20	QA
							a Simvastatin AN	EA
							a Simvastatin-DP	UA
							a Simvastatin-DRLA	RZ
							a Simvastatin-GA 20	GN
							a Simvastatin generichealth	GQ
							a Simvastatin Sandoz	SZ
							a Terry White Chemists Simvastatin	TW
				^B 3.33	13.25	11.07	a Zimstat	AF
							a Lipex 20	FR
							a Zocor	MK
8173E NP	simvastatin 40 mg tablet, 30	1	5	..	11.31	12.46	a APO-Simvastatin	TX
							a Auro-Simvastatin 40	DO
							a Chem mart Simvastatin	CH
							a Ransim	RA
							a Simvacor 40	CR
							a Simvar 40	QA
							a Simvastatin AN	EA
							a Simvastatin-DP	UA
							a Simvastatin-DRLA	RZ

9242K	simvastatin 10 mg tablet, 30	1	11	..	8.95	10.10	^a	APO-Simvastatin	TX
							^a	Auro-Simvastatin 10	DO
							^a	Chem mart Simvastatin	CH
							^a	GenRx Simvastatin	GX
							^a	Ransim	RA
							^a	Simvacor 10	CR
							^a	Simvar 10	QA
							^a	Simvastatin AN	EA
							^a	Simvastatin-DP	UA
							^a	Simvastatin-DRLA	RZ
							^a	Simvastatin-GA 10	GN
							^a	Simvastatin generichealth	GQ
							^a	Simvastatin Sandoz	SZ
							^a	Terry White Chemists Simvastatin	TW
							^a	Zimstat	AF
				^B 3.33	12.28	10.10	^a	Lipex 10	FR
							^a	Zocor	MK
9243L	simvastatin 20 mg tablet, 30	1	11	..	9.92	11.07	^a	APO-Simvastatin	TX
							^a	Auro-Simvastatin 20	DO
							^a	Chem mart Simvastatin	CH
							^a	Ransim	RA

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
9244M	simvastatin 40 mg tablet, 30	1	11	..	11.31	12.46	^a Simvacor 20 CR
							^a Simvar 20 QA
							^a Simvastatin AN EA
							^a Simvastatin-DP UA
							^a Simvastatin-DRLA RZ
							^a Simvastatin-GA 20 GN
							^a Simvastatin GQ
							^a generichealth
							^a Simvastatin Sandoz SZ
							^a Terry White Chemists TW
							^a Simvastatin
							^a Zimstat AF
							^a Lipex 20 FR
							^a Zocor MK
							^a APO-Simvastatin TX
9241J	simvastatin 5 mg tablet, 30	1	11	..	8.35	9.50	^a Auro-Simvastatin 40 DO
							^a Chem mart Simvastatin CH
							^a Ransim RA
							^a Simvacor 40 CR
							^a Simvar 40 QA
							^a Simvastatin AN EA
							^a Simvastatin-DP UA
							^a Simvastatin-DRLA RZ
							^a Simvastatin-GA 40 GN
							^a Simvastatin GQ
							^a generichealth
							^a Simvastatin Sandoz SZ
							^a Terry White Chemists TW
							^a Simvastatin
							^a Zimstat AF
9245N	simvastatin 80 mg tablet, 30	1	11	..	13.29	14.44	^a APO-Simvastatin TX
							^a Auro-Simvastatin 80 DO
							^a Chem mart Simvastatin CH
							^a Ransim RA
							^a Simvacor 80 CR
							^a Simvar 80 QA
							^a Simvastatin AN EA
							^a Simvastatin-DP UA
							^a Simvastatin-DRLA RZ
							^a Simvastatin-GA 80 GN
							^a Simvastatin GQ
							^a generichealth
							^a Simvastatin Sandoz SZ
							^a Terry White Chemists TW
							^a Simvastatin
				^B 3.33	16.62	14.44	^a Zimstat AF
							^a Lipex 80 FR
							^a Zocor MK

Fibrates

FENOFIBRATE

Restricted benefit

For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs

Note

The risk of serious muscle toxicity is increased if fenofibrate is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
9023X NP	fenofibrate 145 mg tablet, 30	1	5	..	42.09	37.70	Lipidil	GO
9022W NP	fenofibrate 48 mg tablet, 60	1	5	..	30.39	31.54	Lipidil	GO

FENOFIBRATE

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

Note

The risk of serious muscle toxicity is increased if fenofibrate is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

9247Q	fenofibrate 145 mg tablet, 30	1	11	..	42.09	37.70	Lipidil	GO
9246P	fenofibrate 48 mg tablet, 60	1	11	..	30.39	31.54	Lipidil	GO

GEMFIBROZIL

Restricted benefit

For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs

Note

The risk of serious muscle toxicity is increased if gemfibrozil is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

1453L NP	gemfibrozil 600 mg tablet, 60	1	5	..	18.15	19.30	^a Ausgem	QA
							^a Chem mart Gemfibrozil	CH
							^a Gemfibrozil-GA	UA
							^a Gemhexal	SZ
							^a GenRx Gemfibrozil	GX
							^a Jezil	GN
							^a Lipigem	AF
							^a Terry White Chemists Gemfibrozil	TW

GEMFIBROZIL

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

Note

The risk of serious muscle toxicity is increased if gemfibrozil is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

9248R	gemfibrozil 600 mg tablet, 60	1	11	..	18.15	19.30	^a Ausgem	QA
							^a Chem mart Gemfibrozil	CH
							^a Gemfibrozil-GA	UA
							^a Gemhexal	SZ
							^a GenRx Gemfibrozil	GX
							^a Jezil	GN
							^a Lipigem	AF
							^a Terry White Chemists Gemfibrozil	TW

Bile acid sequestrants

CHOLESTYRAMINE

2967E	cholestyramine 4 g oral liquid: powder	2	5	..	*72.28	37.70	Questran Lite	QA

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
NP	for, 50 x 4.7 g sachets							
CHOLESTYRAMINE								
<u>Restricted benefit</u>								
For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements								
<u>Note</u>								
No applications for increased maximum quantities and/or repeats will be authorised.								
9249T	cholestyramine 4 g oral liquid: powder for, 50 x 4.7 g sachets	2	11	..	*72.28	37.70	Questran Lite	QA
COLESTIPOL HYDROCHLORIDE								
1224K NP	colestipol hydrochloride 5 g granules, 120 x 5 g sachets	1	5	..	85.38	37.70	Colestid	PF
COLESTIPOL HYDROCHLORIDE								
<u>Restricted benefit</u>								
For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements								
<u>Note</u>								
No applications for increased maximum quantities and/or repeats will be authorised.								
9250W	colestipol hydrochloride 5 g granules, 120 x 5 g sachets	1	11	..	85.38	37.70	Colestid	PF

Other lipid modifying agents

EZETIMIBE

Authority required (STREAMLINED)

3724

Treatment, in conjunction with dietary therapy and exercise, for co-administration with an HMG CoA reductase inhibitor (statin) in patients whose cholesterol levels are inadequately controlled with a statin and who have coronary heart disease. Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated

Authority required (STREAMLINED)

3725

Treatment, in conjunction with dietary therapy and exercise, for co-administration with an HMG CoA reductase inhibitor (statin) in patients whose cholesterol levels are inadequately controlled with a statin and who have diabetes mellitus. Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated

Authority required (STREAMLINED)

3726

Treatment, in conjunction with dietary therapy and exercise, for co-administration with an HMG CoA reductase inhibitor (statin) in patients whose cholesterol levels are inadequately controlled with a statin and who have peripheral vascular disease. Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated

Authority required (STREAMLINED)

3727

Treatment, in conjunction with dietary therapy and exercise, for co-administration with an HMG CoA reductase inhibitor (statin) in patients whose cholesterol levels are inadequately controlled with a statin and who have heterozygous familial hypercholesterolaemia. Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated

Authority required (STREAMLINED)

3728

Treatment, in conjunction with dietary therapy and exercise, for co-administration with an HMG CoA reductase inhibitor (statin) in patients whose cholesterol levels are inadequately controlled with a statin and who have symptomatic cerebrovascular disease. Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated

Authority required (STREAMLINED)

3729

Treatment, in conjunction with dietary therapy and exercise, for co-administration with an HMG CoA reductase inhibitor (statin) in patients whose cholesterol levels are inadequately controlled with a statin and who have family history of coronary heart disease. Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated

Authority required (STREAMLINED)

3730

Treatment, in conjunction with dietary therapy and exercise, for co-administration with an HMG CoA reductase inhibitor (statin) in patients whose cholesterol levels are inadequately controlled with a statin and who have hypertension. Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated						
	Authority required (STREAMLINED)						
	1989						
	Patients eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs) where treatment with an HMG CoA reductase inhibitor (statin) is contraindicated						
	Authority required (STREAMLINED)						
	3731						
	Patients eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs) where treatment with an HMG CoA reductase inhibitor (statin) must be discontinued or reduced because the patient developed a clinically important product-related adverse event during treatment with a statin.						
	A clinically important product-related adverse event is defined as follows:						
	(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or						
	(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or						
	(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin						
	Authority required (STREAMLINED)						
	1991						
	Homozygous sitosterolaemia						
	Authority required (STREAMLINED)						
	2438						
	Patients with homozygous familial hypercholesterolaemia who are eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs), in combination with an HMG CoA reductase inhibitor (statin)						
	Note						
	Continuing Therapy Only:						
	For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.						
8757X NP	ezetimibe 10 mg tablet, 30	1	5	..	71.31	37.70	Ezetrol MK

LIPID MODIFYING AGENTS, COMBINATIONS

HMG CoA reductase inhibitors in combination with other lipid modifying agents

ATORVASTATIN (&) EZETIMIBE

Authority required (STREAMLINED)

4068

Hypercholesterolaemia

Clinical criteria:

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

4085

Hypercholesterolaemia

Clinical criteria:

The treatment must be in conjunction with dietary therapy and exercise,

AND

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

4086

Hypercholesterolaemia

Clinical criteria:

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

4069

Hypercholesterolaemia

Clinical criteria:

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

4096

Hypercholesterolaemia

Clinical criteria:

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	The treatment must be in conjunction with dietary therapy and exercise,						
	AND						
	Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),						
	AND						
	Patient must have symptomatic cerebrovascular disease.						
	Inadequate control with a statin is defined as follows:						
	(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or						
	(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.						
	<u>Authority required (STREAMLINED)</u>						
	4120						
	Hypercholesterolaemia						
	Clinical criteria:						
	The treatment must be in conjunction with dietary therapy and exercise,						
	AND						
	Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),						
	AND						
	Patient must have a family history of coronary heart disease.						
	Inadequate control with a statin is defined as follows:						
	(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or						
	(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.						
	<u>Authority required (STREAMLINED)</u>						
	4121						
	Hypercholesterolaemia						
	Clinical criteria:						
	The treatment must be in conjunction with dietary therapy and exercise,						
	AND						
	Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),						
	AND						
	Patient must have hypertension.						
	Inadequate control with a statin is defined as follows:						
	(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or						
	(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.						
	<u>Authority required (STREAMLINED)</u>						
	4097						

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	Hypercholesterolaemia						
	Clinical criteria:						
	Patient must have homozygous familial hypercholesterolaemia,						
	AND						
	Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).						
	<u>Authority required (STREAMLINED)</u>						
	4353						
	Hypercholesterolaemia						
	Clinical criteria:						
	Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs),						
	AND						
	Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the atorvastatin dose.						
	A clinically important product-related adverse event is defined as follows:						
	(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or						
	(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or						
	(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.						
	<u>Note</u>						
	Continuing Therapy Only:						
	For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.						
10002K NP	atorvastatin 10 mg tablet [30] (& ezetimibe 10 mg tablet [30], 1 pack	\$1	5	..	75.76	37.70	Atozet Composite Pack MK
	ATORVASTATIN (&) EZETIMIBE						
	<u>Authority required (STREAMLINED)</u>						
	4068						
	Hypercholesterolaemia						
	Clinical criteria:						
	The treatment must be in conjunction with dietary therapy and exercise,						
	AND						
	Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),						
	AND						
	Patient must have coronary heart disease.						
	Inadequate control with a statin is defined as follows:						
	(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or						
	(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.						
	<u>Authority required (STREAMLINED)</u>						
	4085						
	Hypercholesterolaemia						
	Clinical criteria:						
	The treatment must be in conjunction with dietary therapy and exercise,						
	AND						
	Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),						
	AND						

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	Patient must have diabetes mellitus.						
	Inadequate control with a statin is defined as follows:						
	(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or						
	(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.						
	<u>Authority required (STREAMLINED)</u>						
	4086						
	Hypercholesterolaemia						
	Clinical criteria:						
	The treatment must be in conjunction with dietary therapy and exercise,						
	AND						
	Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),						
	AND						
	Patient must have peripheral vascular disease.						
	Inadequate control with a statin is defined as follows:						
	(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or						
	(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.						
	<u>Authority required (STREAMLINED)</u>						
	4069						
	Hypercholesterolaemia						
	Clinical criteria:						
	The treatment must be in conjunction with dietary therapy and exercise,						
	AND						
	Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),						
	AND						
	Patient must have heterozygous familial hypercholesterolaemia.						
	Inadequate control with a statin is defined as follows:						
	(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or						
	(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.						
	<u>Authority required (STREAMLINED)</u>						
	4096						
	Hypercholesterolaemia						
	Clinical criteria:						
	The treatment must be in conjunction with dietary therapy and exercise,						
	AND						

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

4120

Hypercholesterolaemia

Clinical criteria:

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

4121

Hypercholesterolaemia

Clinical criteria:

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have hypertension.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

4097

Hypercholesterolaemia

Clinical criteria:

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	Patient must have homozygous familial hypercholesterolaemia,						
	AND						
	Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).						
	Note						
	Continuing Therapy Only:						
	For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.						
2874G NP	atorvastatin 20 mg tablet [30] (& ezetimibe 10 mg tablet [30], 1 pack	£1	5	..	77.88	37.70	Atozet Composite Pack MK
2821L NP	atorvastatin 40 mg tablet [30] (& ezetimibe 10 mg tablet [30], 1 pack	£1	5	..	80.56	37.70	Atozet Composite Pack MK
10006P NP	atorvastatin 80 mg tablet [30] (& ezetimibe 10 mg tablet [30], 1 pack	£1	5	..	84.54	37.70	Atozet Composite Pack MK

EZETIMIBE + SIMVASTATIN

Authority required (STREAMLINED)

4068

Hypercholesterolaemia

Clinical criteria:

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

4085

Hypercholesterolaemia

Clinical criteria:

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

4086

Hypercholesterolaemia

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	Clinical criteria:						
	The treatment must be in conjunction with dietary therapy and exercise,						
	AND						
	Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),						
	AND						
	Patient must have peripheral vascular disease.						
	Inadequate control with a statin is defined as follows:						
	(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or						
	(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.						
	<u>Authority required (STREAMLINED)</u>						
	4069						
	Hypercholesterolaemia						
	Clinical criteria:						
	The treatment must be in conjunction with dietary therapy and exercise,						
	AND						
	Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),						
	AND						
	Patient must have heterozygous familial hypercholesterolaemia.						
	Inadequate control with a statin is defined as follows:						
	(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or						
	(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.						
	<u>Authority required (STREAMLINED)</u>						
	4096						
	Hypercholesterolaemia						
	Clinical criteria:						
	The treatment must be in conjunction with dietary therapy and exercise,						
	AND						
	Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),						
	AND						
	Patient must have symptomatic cerebrovascular disease.						
	Inadequate control with a statin is defined as follows:						
	(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or						
	(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.						
	Authority required (STREAMLINED)						

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
4120	Hypercholesterolaemia						
	Clinical criteria:						
	The treatment must be in conjunction with dietary therapy and exercise,						
	AND						
	Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),						
	AND						
	Patient must have a family history of coronary heart disease.						
	Inadequate control with a statin is defined as follows:						
	(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or						
	(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.						
	<u>Authority required (STREAMLINED)</u>						
4121	Hypercholesterolaemia						
	Clinical criteria:						
	The treatment must be in conjunction with dietary therapy and exercise,						
	AND						
	Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),						
	AND						
	Patient must have hypertension.						
	Inadequate control with a statin is defined as follows:						
	(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or						
	(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.						
	<u>Authority required (STREAMLINED)</u>						
4097	Hypercholesterolaemia						
	Clinical criteria:						
	Patient must have homozygous familial hypercholesterolaemia,						
	AND						
	Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).						
	<u>Authority required (STREAMLINED)</u>						
4147	Hypercholesterolaemia						
	Clinical criteria:						
	Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs),						
	AND						
	Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose.						
	A clinically important product-related adverse event is defined as follows:						

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.							
	Note							
	Continuing Therapy Only:							
	For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
9483D NP	ezetimibe 10 mg + simvastatin 10 mg tablet, 30	1	5	..	73.41	37.70	Vytorin	MK
9484E NP	ezetimibe 10 mg + simvastatin 20 mg tablet, 30	1	5	..	74.34	37.70	Vytorin	MK

EZETIMIBE + SIMVASTATIN

Authority required (STREAMLINED)

4068

Hypercholesterolaemia

Clinical criteria:

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

4085

Hypercholesterolaemia

Clinical criteria:

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

4086

Hypercholesterolaemia

Clinical criteria:

The treatment must be in conjunction with dietary therapy and exercise,

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	AND						
	Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),						
	AND						
	Patient must have peripheral vascular disease.						
	Inadequate control with a statin is defined as follows:						
	(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or						
	(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.						
	<u>Authority required (STREAMLINED)</u>						
	4069						
	Hypercholesterolaemia						
	Clinical criteria:						
	The treatment must be in conjunction with dietary therapy and exercise,						
	AND						
	Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),						
	AND						
	Patient must have heterozygous familial hypercholesterolaemia.						
	Inadequate control with a statin is defined as follows:						
	(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or						
	(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.						
	<u>Authority required (STREAMLINED)</u>						
	4096						
	Hypercholesterolaemia						
	Clinical criteria:						
	The treatment must be in conjunction with dietary therapy and exercise,						
	AND						
	Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),						
	AND						
	Patient must have symptomatic cerebrovascular disease.						
	Inadequate control with a statin is defined as follows:						
	(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or						
	(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.						
	<u>Authority required (STREAMLINED)</u>						
	4120						
	Hypercholesterolaemia						

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
Clinical criteria:								
The treatment must be in conjunction with dietary therapy and exercise,								
AND								
Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),								
AND								
Patient must have a family history of coronary heart disease.								
Inadequate control with a statin is defined as follows:								
(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or								
(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.								
<u>Authority required (STREAMLINED)</u>								
4121								
Hypercholesterolaemia								
Clinical criteria:								
The treatment must be in conjunction with dietary therapy and exercise,								
AND								
Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),								
AND								
Patient must have hypertension.								
Inadequate control with a statin is defined as follows:								
(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or								
(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.								
<u>Authority required (STREAMLINED)</u>								
4097								
Hypercholesterolaemia								
Clinical criteria:								
Patient must have homozygous familial hypercholesterolaemia,								
AND								
Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).								
<u>Note</u>								
Continuing Therapy Only:								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8881K NP	ezetimibe 10 mg + simvastatin 40 mg tablet, 30	1	5	..	75.66	37.70	Vytorin	MK
8882L NP	ezetimibe 10 mg + simvastatin 80 mg tablet, 30	1	5	..	77.56	37.70	Vytorin	MK

ROSUVASTATIN (&) EZETIMIBE

Authority required (STREAMLINED)

4068

Hypercholesterolaemia

Clinical criteria:

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	The treatment must be in conjunction with dietary therapy and exercise,						
	AND						
	Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),						
	AND						
	Patient must have coronary heart disease.						
	Inadequate control with a statin is defined as follows:						
	(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or						
	(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.						
	<u>Authority required (STREAMLINED)</u>						
	4085						
	Hypercholesterolaemia						
	Clinical criteria:						
	The treatment must be in conjunction with dietary therapy and exercise,						
	AND						
	Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),						
	AND						
	Patient must have diabetes mellitus.						
	Inadequate control with a statin is defined as follows:						
	(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or						
	(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.						
	<u>Authority required (STREAMLINED)</u>						
	4086						
	Hypercholesterolaemia						
	Clinical criteria:						
	The treatment must be in conjunction with dietary therapy and exercise,						
	AND						
	Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),						
	AND						
	Patient must have peripheral vascular disease.						
	Inadequate control with a statin is defined as follows:						
	(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or						
	(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.						
	<u>Authority required (STREAMLINED)</u>						
	4069						

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	Hypercholesterolaemia						
	Clinical criteria:						
	The treatment must be in conjunction with dietary therapy and exercise,						
	AND						
	Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),						
	AND						
	Patient must have heterozygous familial hypercholesterolaemia.						
	Inadequate control with a statin is defined as follows:						
	(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or						
	(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.						
	<u>Authority required (STREAMLINED)</u>						
	4096						
	Hypercholesterolaemia						
	Clinical criteria:						
	The treatment must be in conjunction with dietary therapy and exercise,						
	AND						
	Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),						
	AND						
	Patient must have symptomatic cerebrovascular disease.						
	Inadequate control with a statin is defined as follows:						
	(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or						
	(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.						
	<u>Authority required (STREAMLINED)</u>						
	4120						
	Hypercholesterolaemia						
	Clinical criteria:						
	The treatment must be in conjunction with dietary therapy and exercise,						
	AND						
	Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),						
	AND						
	Patient must have a family history of coronary heart disease.						
	Inadequate control with a statin is defined as follows:						
	(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or						
	(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.						

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

Authority required (STREAMLINED)

4121

Hypercholesterolaemia

Clinical criteria:

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have hypertension.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

4097

Hypercholesterolaemia

Clinical criteria:

Patient must have homozygous familial hypercholesterolaemia,

AND

Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

10208G NP	rosuvastatin 10 mg tablet [30] (&) ezetimibe 10 mg tablet [30], 1 pack	£1	5	..	78.54	37.70	Rosuzet Composite Pack	MK
10201X NP	rosuvastatin 20 mg tablet [30] (&) ezetimibe 10 mg tablet [30], 1 pack	£1	5	..	81.48	37.70	Rosuzet Composite Pack	MK
10207F NP	rosuvastatin 40 mg tablet [30] (&) ezetimibe 10 mg tablet [30 tablets], 1 pack	£1	5	..	85.86	37.70	Rosuzet Composite Pack	MK

ROSUVASTATIN (&) EZETIMIBE

Authority required (STREAMLINED)

4068

Hypercholesterolaemia

Clinical criteria:

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

4085

Hypercholesterolaemia

Clinical criteria:

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

4086

Hypercholesterolaemia

Clinical criteria:

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

4069

Hypercholesterolaemia

Clinical criteria:

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.						
	<u>Authority required (STREAMLINED)</u>						
	4096						
	Hypercholesterolaemia						
	Clinical criteria:						
	The treatment must be in conjunction with dietary therapy and exercise,						
	AND						
	Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),						
	AND						
	Patient must have symptomatic cerebrovascular disease.						
	Inadequate control with a statin is defined as follows:						
	(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or						
	(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.						
	<u>Authority required (STREAMLINED)</u>						
	4120						
	Hypercholesterolaemia						
	Clinical criteria:						
	The treatment must be in conjunction with dietary therapy and exercise,						
	AND						
	Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),						
	AND						
	Patient must have a family history of coronary heart disease.						
	Inadequate control with a statin is defined as follows:						
	(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or						
	(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.						
	<u>Authority required (STREAMLINED)</u>						
	4121						
	Hypercholesterolaemia						
	Clinical criteria:						
	The treatment must be in conjunction with dietary therapy and exercise,						
	AND						
	Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),						
	AND						
	Patient must have hypertension.						
	Inadequate control with a statin is defined as follows:						
	(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.						

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or						
	(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.						
	<u>Authority required (STREAMLINED)</u>						
	4097						
	Hypercholesterolaemia						
	Clinical criteria:						
	Patient must have homozygous familial hypercholesterolaemia,						
	AND						
	Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).						
	<u>Authority required (STREAMLINED)</u>						
	4147						
	Hypercholesterolaemia						
	Clinical criteria:						
	Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs),						
	AND						
	Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose.						
	A clinically important product-related adverse event is defined as follows:						
	(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or						
	(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or						
	(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.						
	<u>Note</u>						
	Continuing Therapy Only:						
	For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.						
10204C NP	rosuvastatin 5 mg tablet [30] (& ezetimibe 10 mg tablet [30], 1 pack	±1	5	..	76.21	37.70	Rosuzet Composite Pack MK
	<i>HMG CoA reductase inhibitors, other combinations</i>						
	AMLODIPINE + ATORVASTATIN						
	<u>Restricted benefit</u>						
	For use in patients who have hypertension and/or angina and who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are currently receiving treatment with a dihydropyridine calcium channel blocker						
	<u>Restricted benefit</u>						
	For use in patients who have hypertension and/or angina and who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and whose blood pressure and/or angina is inadequately controlled with other classes of antihypertensive and/or anti-anginal agent, and in whom adjunctive therapy with a dihydropyridine calcium channel blocker would be appropriate						
	<u>Restricted benefit</u>						
	For use in patients who have hypertension and/or angina and who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are intolerant of the side effects of other classes of antihypertensive and/or anti-anginal agent, and in whom replacement therapy with a dihydropyridine calcium channel blocker would be appropriate						
9053L NP	amlodipine 10 mg + atorvastatin 10 mg tablet, 30	1	5	..	45.64	37.70	^a APO- Amlodipine/Atorvastatin 10/10 TX ^a Blooms the Chemist Amlodipine/Atorvastatin 10/10 IB ^a Cadatin 10/10 FZ ^a Cadivast 10/10 AF ^a Caduet 10/10 PF ^a Chem mart Amlodipine/Atorvastatin 10/10 CH

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
9054M NP	amlodipine 10 mg + atorvastatin 20 mg tablet, 30	1	5	..	58.54	37.70	a Terry White Chemists Amlodipine/Atorvastatin 10/10	TW
							a APO- Amlodipine/Atorvastatin 10/20	TX
							a Blooms the Chemist Amlodipine/Atorvastatin 10/20	IB
							a Cadatin 10/20	FZ
							a Cadivast 10/20	AF
							a Caduet 10/20	PF
							a Chem mart Amlodipine/Atorvastatin 10/20	CH
9055N NP	amlodipine 10 mg + atorvastatin 40 mg tablet, 30	1	5	..	76.23	37.70	a Terry White Chemists Amlodipine/Atorvastatin 10/20	TW
							a APO- Amlodipine/Atorvastatin 10/40	TX
							a Blooms the Chemist Amlodipine/Atorvastatin 10/40	IB
							a Cadatin 10/40	FZ
							a Cadivast 10/40	AF
							a Caduet 10/40	PF
							a Chem mart Amlodipine/Atorvastatin 10/40	CH
9056P NP	amlodipine 10 mg + atorvastatin 80 mg tablet, 30	1	5	..	102.43	37.70	a Terry White Chemists Amlodipine/Atorvastatin 10/40	TW
							a APO- Amlodipine/Atorvastatin 10/80	TX
							a Blooms the Chemist Amlodipine/Atorvastatin 10/80	IB
							a Cadatin 10/80	FZ
							a Cadivast 10/80	AF
							a Caduet 10/80	PF
							a Chem mart Amlodipine/Atorvastatin 10/80	CH
9049G NP	amlodipine 5 mg + atorvastatin 10 mg tablet, 30	1	5	..	42.34	37.70	a Terry White Chemists Amlodipine/Atorvastatin 10/80	TW
							a APO- Amlodipine/Atorvastatin 5/10	TX
							a Blooms the Chemist Amlodipine/Atorvastatin 5/10	IB
							a Cadatin 5/10	FZ
							a Cadivast 5/10	AF
							a Caduet 5/10	PF
							a Chem mart Amlodipine/Atorvastatin 5/10	CH
9050H NP	amlodipine 5 mg + atorvastatin 20 mg tablet, 30	1	5	..	55.03	37.70	a Terry White Chemists Amlodipine/Atorvastatin 5/10	TW
							a APO- Amlodipine/Atorvastatin 5/20	TX
							a Blooms the Chemist Amlodipine/Atorvastatin 5/20	IB

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
9051J NP	amlodipine 5 mg + atorvastatin 40 mg tablet, 30	1	5	..	72.60	37.70	a Cadatin 5/20	FZ
							a Cadivast 5/20	AF
							a Caduet 5/20	PF
							a Chem mart	CH
							Amlodipine/Atorvastatin 5/20	
							a Terry White Chemists	TW
							Amlodipine/Atorvastatin 5/20	
							a APO-	TX
							Amlodipine/Atorvastatin 5/40	
							a Blooms the Chemist	IB
							Amlodipine/Atorvastatin 5/40	
							a Cadatin 5/40	FZ
							a Cadivast 5/40	AF
							a Caduet 5/40	PF
9052K NP	amlodipine 5 mg + atorvastatin 80 mg tablet, 30	1	5	..	98.80	37.70	a Chem mart	CH
							Amlodipine/Atorvastatin 5/40	
							a Terry White Chemists	TW
							Amlodipine/Atorvastatin 5/40	
							a APO-	TX
							Amlodipine/Atorvastatin 5/80	
							a Blooms the Chemist	IB
							Amlodipine/Atorvastatin 5/80	
							a Cadatin 5/80	FZ
							a Cadivast 5/80	AF
							a Caduet 5/80	PF
							a Chem mart	CH
							Amlodipine/Atorvastatin 5/80	
							a Terry White Chemists	TW
							Amlodipine/Atorvastatin 5/80	

DERMATOLOGICALS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

DERMATOLOGICALS

ANTIFUNGALS FOR DERMATOLOGICAL USE

ANTIFUNGALS FOR TOPICAL USE

Antibiotics

NYSTATIN

Authority required (STREAMLINED)

2354

Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person

1698J NP	nystatin 100 000 international units/g cream, 15 g	2	3	..	*18.90	20.05	Mycostatin	FM

Imidazole and triazole derivatives

KETOCONAZOLE

Authority required (STREAMLINED)

2354

Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person

9025B NP	ketoconazole 1% (10 mg/g) shampoo, 100 mL	\$1	1	..	17.94	19.09	Nizoral 1%	JT
9024Y NP	ketoconazole 2% (20 mg/g) cream, 30 g	\$1	2	..	23.46	24.61	Nizoral 2% Cream	JT
1574W NP	ketoconazole 2% (20 mg/g) shampoo, 60 mL	\$1	1	..	18.65	19.80	Nizoral 2%	JT

MICONAZOLE

Authority required (STREAMLINED)

2354

Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person

9031H NP	miconazole 2% solution, 30 mL	\$1	2	..	19.81	20.96	Daktarin Tincture	JT
9027D NP	miconazole nitrate 2% (20 mg/g) cream, 30 g	\$1	2	..	15.13	16.28	Daktarin	JT
9028E NP	miconazole nitrate 2% (20 mg/g) cream, 70 g	\$1	1	..	17.13	18.28	Daktarin	JT
9029F NP	miconazole nitrate 2% (20 mg/g) powder: dusting, 30 g	\$1	2	..	15.90	17.05	Daktarin	JT

Other antifungals for topical use

TERBINAFINE

Authority required (STREAMLINED)

2354

Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person

Authority required (STREAMLINED)

3243

Treatment of a fungal or a yeast infection in a patient aged up to 18 years inclusive

9160D NP	terbinafine hydrochloride 1% cream, 15 g	2	3	..	*37.70	37.70	Lamisil	NC

ANTIFUNGALS FOR SYSTEMIC USE

Antifungals for systemic use

GRISEOFULVIN

1460W NP	griseofulvin 125 mg tablet, 100	1	2	..	26.21	27.36	Grisovin	QA
2982Y NP	griseofulvin 500 mg tablet, 28	1	2	..	27.33	28.48	Grisovin 500	QA

TERBINAFINE

Authority required

Treatment of a dermatophyte infection in an Aboriginal or a Torres Strait Islander person where topical treatment has failed

Authority required

Treatment of a dermatophyte infection in a patient aged up to 18 years inclusive where topical treatment and griseofulvin have failed

2285G	terbinafine 250 mg tablet, 42	1	..	..	38.82	37.70 ^a	GenRx Terbinafine	GX

DERMATOLOGICALS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
NP								
							a Lamisil (Novartis Pharmaceuticals Australia Pty Limited)	NV
							a Pharmacy Choice Terbinafine	RI
							a Sebifin 250	RA
							a Tamsil	QA
							a Terbinafine Actavis	VN
							a Terbinafine AN	EA
							a Terbinafine-DRLA	RZ
							a Terbinafine GH	GQ
							a Terbinafine Sandoz	SZ
							a Tinasil	AF

TERBINAFINE

Authority required

Proximal or extensive (greater than 80% nail involvement) onychomycosis due to dermatophyte infection where topical treatment has failed. This infection must be proven by microscopy or culture and confirmed by an Approved Pathology Authority. The date of the pathology report must be provided at the time of application and must not be more than 12 months old

Note

No applications for increased maximum quantities and/or repeats will be authorised.

2804N	terbinafine 250 mg tablet, 42	1	1	..	38.82	37.70	a GenRx Terbinafine	GX
NP							a Lamisil (Novartis Pharmaceuticals Australia Pty Limited)	NV
							a Pharmacy Choice Terbinafine	RI
							a Sebifin 250	RA
							a Tamsil	QA
							a Terbinafine Actavis	VN
							a Terbinafine AN	EA
							a Terbinafine-DRLA	RZ
							a Terbinafine GH	GQ
							a Terbinafine Sandoz	SZ
							a Tinasil	AF

ANTIPSORIATICS

ANTIPSORIATICS FOR TOPICAL USE

Tars

COAL TAR PREPARED

8864M	coal tar prepared 1% (10 mg/g) lotion, 100 mL	‡1	2	..	33.42	34.57	Exorex	GN
NP								
10225E	coal tar prepared 2% foam, 100 g	‡1	2	..	33.42	34.57	Scytera	RZ
NP								

Other antipsoriatics for topical use

CALCIPOTRIOL

Restricted benefit

Chronic stable plaque type psoriasis vulgaris

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2080L	calcipotriol 0.005% cream, 30 g	‡1	1	..	28.40	29.55	Daivonex	LO
NP								

CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE

Restricted benefit

Chronic stable plaque type psoriasis vulgaris of the scalp in a patient who is not adequately controlled with either calcipotriol or potent topical corticosteroid monotherapy

Note

DERMATOLOGICALS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
Continuing Therapy Only:								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
5276Q NP	calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% gel, 30 g	\$1	1	..	42.23	37.70	Daivobet 50/500 gel	LO
CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE								
<u>Authority required</u>								
Chronic stable plaque type psoriasis vulgaris								
<u>Clinical criteria:</u>								
The condition must be on the patient's scalp,								
AND								
The condition must be inadequately controlled with either a vitamin D analogue or potent topical corticosteroid as monotherapy,								
AND								
Patient must require more than 30 grams of the product per month.								
<u>Note</u>								
Continuing Therapy Only:								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
10075G NP	betamethasone (as dipropionate) 0.05% + calcipotriol 0.005% gel, 60 g	\$1	1	..	74.88	37.70	Daivobet 50/500 gel	LO
CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE								
<u>Restricted benefit</u>								
Chronic stable plaque type psoriasis vulgaris in a patient who is not adequately controlled with either calcipotriol or potent topical corticosteroid monotherapy								
<u>Note</u>								
Continuing Therapy Only:								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
9494Q NP	calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% ointment, 30 g	\$1	1	..	42.23	37.70	Daivobet	LO
ANTIPSORIATICS FOR SYSTEMIC USE								
<i>Retinoids for treatment of psoriasis</i>								
ACITRETIN								
<u>Authority required (STREAMLINED)</u>								
1366								
Severe intractable psoriasis								
<u>Authority required (STREAMLINED)</u>								
1363								
Severe forms of disorders of keratinisation								
<u>Caution</u>								
This drug is a potent teratogen—pregnancy should be avoided for at least two years after cessation of therapy.								
<u>Note</u>								
Care must be taken to comply with the provisions of State/Territory law when prescribing acitretin.								
2019G	acitretin 10 mg capsule, 100	1	2	..	174.32	37.70	^a Acitretin Actavis	GN
							^a Neotigason	UA
							^a Novatin	TX
2020H	acitretin 25 mg capsule, 100	1	2	..	334.55	37.70	^a Acitretin Actavis	GN
							^a Neotigason	UA
							^a Novatin	TX

ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE

CHEMOTHERAPEUTICS FOR TOPICAL USE

Sulfonamides

DERMATOLOGICALS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
SULFADIAZINE SILVER								
<u>Restricted benefit</u>								
Prevention and treatment of infection in partial or full skin thickness loss due to burns								
<u>Restricted benefit</u>								
Prevention and treatment of infection in partial or full skin thickness loss due to epidermolysis bullosa								
<u>Restricted benefit</u>								
Stasis ulcers								
9479X NP	sulfadiazine silver 1% (10 mg/g) cream, 50 g	\$1	..	..	19.49	20.64	Flamazine	SN

CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS

CORTICOSTEROIDS, PLAIN

Corticosteroids, weak (group I)

HYDROCORTISONE ACETATE

Restricted benefit

Treatment of corticosteroid-responsive dermatoses

2887Y NP	hydrocortisone acetate 1% (10 mg/g) cream, 30 g	\$1	1	..	9.23	10.38	^a Cortic-DS 1%	FM
				^B 2.69	11.92	10.38	^a Sigmacort	QA
5111B DP	hydrocortisone acetate 1% (10 mg/g) cream, 30 g	\$1	..	..	9.23	10.38	^a Cortic-DS 1%	FM
				^B 2.69	11.92	10.38	^a Sigmacort	QA
2881P NP	hydrocortisone acetate 1% (10 mg/g) cream, 50 g	\$1	1	..	8.90	10.05	^a Cortic-DS 1%	FM
				^B 2.70	11.60	10.05	^a Sigmacort	QA
5113D DP	hydrocortisone acetate 1% (10 mg/g) cream, 50 g	\$1	..	..	8.90	10.05	^a Cortic-DS 1%	FM
				^B 2.70	11.60	10.05	^a Sigmacort	QA
2888B NP	hydrocortisone acetate 1% (10 mg/g) ointment, 30 g	\$1	1	..	9.23	10.38	^a Cortic-DS 1%	FM
				^B 2.69	11.92	10.38	^a Sigmacort	QA
5112C DP	hydrocortisone acetate 1% (10 mg/g) ointment, 30 g	\$1	..	..	9.23	10.38	^a Cortic-DS 1%	FM
				^B 2.69	11.92	10.38	^a Sigmacort	QA
2882Q NP	hydrocortisone acetate 1% (10 mg/g) ointment, 50 g	\$1	1	..	8.90	10.05	^a Cortic-DS 1%	FM
				^B 2.70	11.60	10.05	^a Sigmacort	QA
5114E DP	hydrocortisone acetate 1% (10 mg/g) ointment, 50 g	\$1	..	..	8.90	10.05	^a Cortic-DS 1%	FM
				^B 2.70	11.60	10.05	^a Sigmacort	QA

Corticosteroids, moderately potent (group II)

TRIAMCINOLONE

Restricted benefit

Treatment of corticosteroid-responsive dermatoses

2117K NP	triamcinolone acetonide 0.02% (200 microgram/g) cream, 100 g	2	..	..	*14.74	15.89	^a Tricortone	FM
				^B 3.78	*18.52	15.89	^a Aristocort 0.02%	QA
2118L NP	triamcinolone acetonide 0.02% (200 microgram/g) ointment, 100 g	2	..	..	*14.74	15.89	^a Tricortone	FM
				^B 3.78	*18.52	15.89	^a Aristocort 0.02%	QA

Corticosteroids, potent (group III)

BETAMETHASONE DIPROPIONATE

Restricted benefit

Treatment of corticosteroid-responsive dermatoses

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1115Q	betamethasone (as dipropionate)	\$1	1	..	13.48	14.63	^a Eleuphrat	FR

DERMATOLOGICALS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
NP	0.05% cream, 15 g			^B 2.45	15.93	14.63	^a Diprosone	MK
1119X	betamethasone (as dipropionate)	‡1	1	..	13.48	14.63	^a Eleuphrat	FR
NP	0.05% ointment, 15 g			^B 2.45	15.93	14.63	^a Diprosone	MK
BETAMETHASONE VALERATE								
<u>Restricted benefit</u>								
Treatment of corticosteroid-responsive dermatoses								
2812B	betamethasone (as valerate) 0.02% (200 microgram/g) cream, 100 g	2	..	..	*24.56	25.71	^b Cortival 1/5	FM
NP				^B 2.46	*27.02	25.71	^a Antroquoril	FR
				^B 6.88	*31.44	25.71	^a Celestone-M	MK
							^b Betnovate 1/5	QA
BETAMETHASONE VALERATE								
<u>Restricted benefit</u>								
Treatment of corticosteroid-responsive dermatoses								
<u>Note</u>								
Continuing Therapy Only:								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
2813C	betamethasone (as valerate) 0.05% (500 microgram/g) cream, 15 g	‡1	1	..	8.75	9.90	^a Cortival 1/2	FM
NP				^B 2.94	11.69	9.90	^a Betnovate 1/2	QA
METHYLPREDNISOLONE								
<u>Restricted benefit</u>								
Treatment of corticosteroid-responsive dermatoses								
<u>Note</u>								
Continuing Therapy Only:								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8054X	methylprednisolone aceponate 0.1% (1 mg/g) cream, 15 g	‡1	..	..	14.32	15.47	Advantan	BN
NP								
8055Y	methylprednisolone aceponate 0.1% (1 mg/g) ointment, 15 g	‡1	..	..	14.32	15.47	Advantan	BN
NP								
8128T	methylprednisolone aceponate 0.1% (1 mg/g) ointment, 15 g	‡1	..	..	14.32	15.47	Advantan	BN
NP								
METHYLPREDNISOLONE								
<u>Restricted benefit</u>								
Eczema								
<u>Note</u>								
Continuing Therapy Only:								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8618N	methylprednisolone aceponate 0.1% (1 mg/g) lotion, 20 g	‡1	..	..	14.99	16.14	Advantan	BN
NP								
MOMETASONE								
<u>Restricted benefit</u>								
Treatment of corticosteroid-responsive dermatoses								
<u>Note</u>								
Continuing Therapy Only:								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
1913Q	mometasone furoate 0.1% (1 mg/g) cream, 15 g	‡1	..	..	12.35	13.50	^a Momasone	QA
NP							^a Novasone	FR
				^B 3.07	15.42	13.50	^a Elocon	MK
8043H	mometasone furoate 0.1% lotion, 30 mL	‡1	..	..	15.58	16.73	^a Novasone	FR
NP								

DERMATOLOGICALS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
1915T NP	mometasone furoate 0.1% ointment, 15 g	‡1	..	^B 3.06	18.64	16.73	^a Zatamil	EO
				..	12.35	13.50	^a Elocon	MK
				..	..	..	^a Novasone	FR
				^B 3.07	15.42	13.50	^a Zatamil	EO
							^a Elocon	MK

Corticosteroids, very potent (group IV)

CLOBETASOL

Authority required

Moderate to severe scalp psoriasis

Clinical criteria:

The condition must be inadequately controlled with either a vitamin D analogue or potent topical corticosteroid as monotherapy; OR

The condition must be inadequately controlled with combination use of a vitamin D analogue and potent topical corticosteroid.

Population criteria:

Patient must be aged 18 years or older.

10080M	clobetasol propionate 0.05% shampoo, 125 mL	‡1	1	..	48.98	37.70	Clobex	GA

ANTI-ACNE PREPARATIONS

ANTI-ACNE PREPARATIONS FOR TOPICAL USE

Retinoids for topical use in acne

ADAPALENE + BENZOYL PEROXIDE

Restricted benefit

Acute treatment, in combination with an oral antibiotic, of severe acne vulgaris

8954G	adapalene 0.1% + benzoyl peroxide 2.5% gel, 30 g	‡1	1	..	37.27	37.70	Epiduo	GA

ADAPALENE + BENZOYL PEROXIDE

Restricted benefit

Maintenance treatment of severe acne vulgaris

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8955H NP	adapalene 0.1% + benzoyl peroxide 2.5% gel, 30 g	‡1	3	..	37.27	37.70	Epiduo	GA

ANTI-ACNE PREPARATIONS FOR SYSTEMIC USE

Retinoids for treatment of acne

ISOTRETINOIN

Authority required (STREAMLINED)

1354

Severe cystic acne not responsive to other therapy

Caution

This drug causes birth defects. Isotretinoin has been reported to cause other frequent and potentially serious toxicity.

Note

Care must be taken to comply with the provisions of State/Territory law when prescribing isotretinoin.

2591J	isotretinoin 10 mg capsule, 60	1	3	..	43.29	37.70	^a APO-Isotretinoin	TX
							^a Dermatane	ER
							^a Isotretinoin AN	EA
							^a Isotretinoin SCP 10	CR
							^a Oratane	GN
							^a Roaccutane	RO
							^a Rocta 10	QA
2592K	isotretinoin 20 mg capsule, 60	1	3	..	61.66	37.70	^a APO-Isotretinoin	TX
							^a Dermatane	ER

DERMATOLOGICALS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							a Isotretinoin AN	EA
							a Isotretinoin SCP 20	CR
							a Oratane	GN
							a Roaccutane	RO
							a Rocta 20	QA
2549E	isotretinoin 40 mg capsule, 30	1	3	..	56.32	37.70	a Dermatane	ER
							a Oratane	GN

OTHER DERMATOLOGICAL PREPARATIONS

OTHER DERMATOLOGICAL PREPARATIONS

Agents for dermatitis, excluding corticosteroids

PIMECROLIMUS

Authority required

Treatment of facial or eyelid atopic dermatitis in patients aged at least 3 months with 1 or more of the following contraindications to topical corticosteroids:

- (i) perioral dermatitis;
- (ii) periorbital dermatitis;
- (iii) rosacea;
- (iv) epidermal atrophy;
- (v) dermal atrophy;
- (vi) allergy to topical corticosteroids;
- (vii) cataracts;
- (viii) glaucoma;
- (ix) raised intraocular pressure

Authority required

Short-term (up to 3 weeks) intermittent treatment of atopic dermatitis of the face or eyelids in patients aged at least 3 months who fail to achieve satisfactory disease control with intermittent topical corticosteroid therapy, and where more than 3 months have passed since the initial diagnosis of atopic dermatitis.

Failure to achieve satisfactory disease control with intermittent topical corticosteroid therapy is manifest by:

- (i) failure of the facial skin to clear despite at least 2 weeks of topical hydrocortisone 1% applied every day; or
- (ii) failure of the facial skin to clear despite at least 1 week of a moderate or potent topical corticosteroid applied every day; or
- (iii) clearing of the facial skin with at least 2 weeks of topical hydrocortisone 1% applied every day, but almost immediate and significant flare in facial disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2 consecutive occasions; or
- (iv) clearing of the facial skin with at least 1 week of a moderate or potent topical corticosteroid applied every day, but almost immediate and significant flare in facial disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2 consecutive occasions

Note

No applications for increased maximum quantities and/or repeats will be authorised. Only 1 authority application per 6 months, per patient, will be authorised.

8802G	pimecrolimus 1% (10 mg/g) cream, 15 g	±1	1	..	34.13	35.28	Elidel	HM

Other dermatologicals

DAPSONE

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1272Y NP	dapsone 100 mg tablet, 100	1	1	..	114.18	37.70	Link Medical Products Pty Ltd	LM
8801F NP	dapsone 25 mg tablet, 100	1	1	..	100.92	37.70	Link Medical Products Pty Ltd	LM

IMIQUIMOD

Authority required

Superficial basal cell carcinoma

Clinical criteria:

DERMATOLOGICALS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	The condition must be previously untreated, AND The condition must be confirmed by biopsy, AND Patient must have normal immune function, AND The condition must not be suitable for treatment with surgical excision; OR The condition must not be suitable for treatment with cryotherapy; OR The condition must not be suitable for treatment with curettage with diathermy, AND Patient must require topical drug therapy. The date of the pathology report and name of the Approved Pathology Authority must be provided at the time of application. Note The patient or carer must be able to understand and administer the imiquimod dosing regimen. Note No increase in the maximum quantity or number of units may be authorised. Note No increase in the maximum number of repeats may be authorised. Note Treatment of recurrent (previously treated) lesions will not be authorised. Note Pharmaceutical benefits that have the form imiquimod single use sachets and pharmaceutical benefits that have the form imiquimod multi-use pump are equivalent for the purposes of substitution.						
2546B	imiquimod 5% cream, 12 x 250 mg sachets	1	1	..	135.72	37.70	^a Aldara IA
							^a Aldiq QA
							^a APO-Imiquimod TX
2637T	imiquimod 5% cream, 2 x 2 g pump packs	1	1	..	135.72	37.70	^a Aldara Pump IA

GENITO URINARY SYSTEM AND SEX HORMONES

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

GENITO URINARY SYSTEM AND SEX HORMONES

OTHER GYNECOLOGICALS

OXYTOCICS

Prostaglandins

MIFEPRISTONE (&) MISOPROSTOL

Authority required

Termination of an intra-uterine pregnancy

Clinical criteria:

The condition must be an intra-uterine pregnancy of up to 63 days of gestation.

Treatment criteria:

Must be treated by a prescriber who is registered with the MS 2 Step Prescribing Program.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

10211K	mifepristone 200 mg tablet [1] (&) misoprostol 200 microgram tablet [4], 1 pack	1	..	..	321.38	37.70	MS-2 Step	XH

CONTRACEPTIVES FOR TOPICAL USE

Intrauterine contraceptives

LEVONORGESTREL

Restricted benefit

Contraception

Restricted benefit

Idiopathic menorrhagia where oral treatments are ineffective

Restricted benefit

Idiopathic menorrhagia where oral treatments are contraindicated

8633J NP	levonorgestrel 52 mg drug delivery system: intrauterine, 1 system	1	..	..	266.56	37.70	Mirena	BN

OTHER GYNECOLOGICALS

Prolactine inhibitors

BROMOCRIPTINE

Restricted benefit

Acromegaly

Restricted benefit

Parkinson's disease

Restricted benefit

Pathological hyperprolactinaemia where surgery is not indicated

Restricted benefit

Pathological hyperprolactinaemia where surgery has already been used with incomplete resolution

Restricted benefit

Pathological hyperprolactinaemia where radiotherapy is not indicated

Restricted benefit

Pathological hyperprolactinaemia where radiotherapy has already been used with incomplete resolution

Note

Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

Note

For item codes 1443Y and 1559C, pharmaceutical benefits that have the form tablet 2.5 mg (base) are equivalent for the purposes of substitution.

1443Y	bromocriptine 2.5 mg tablet, 30	2	5	..	*31.76	32.91 ^a	Parlodel	NV
1559C	bromocriptine 2.5 mg tablet, 60	1	5	..	31.76	32.91 ^a	Kripton 2.5	AF

GENITO URINARY SYSTEM AND SEX HORMONES

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
BROMOCRIPTINE								
<u>Restricted benefit</u>								
Prevention of the onset of lactation in the puerperium for medical reasons								
1444B NP	bromocriptine 2.5 mg tablet, 30	1	..	..	19.26	20.41	a Krypton 2.5	AF
							a Parlodel	NV
CABERGOLINE								
<u>Restricted benefit</u>								
Prevention of the onset of lactation in the puerperium for medical reasons								
8115D NP	cabergoline 500 microgram tablet, 2	1	..	..	22.12	23.27	a Dostan	GN
							a Dostinex	PF
CABERGOLINE								
<u>Authority required (STREAMLINED)</u>								
2659								
Pathological hyperprolactinaemia where surgery is not indicated								
<u>Authority required (STREAMLINED)</u>								
2660								
Pathological hyperprolactinaemia where surgery has already been used with incomplete resolution								
<u>Authority required (STREAMLINED)</u>								
2661								
Pathological hyperprolactinaemia where radiotherapy is not indicated								
<u>Authority required (STREAMLINED)</u>								
2662								
Pathological hyperprolactinaemia where radiotherapy has already been used with incomplete resolution								
8114C	cabergoline 500 microgram tablet, 8	1	5	..	65.57	37.70	a Dostan	GN
							a Dostinex	PF
QUINAGOLIDE								
<u>Authority required (STREAMLINED)</u>								
2659								
Pathological hyperprolactinaemia where surgery is not indicated								
<u>Authority required (STREAMLINED)</u>								
2660								
Pathological hyperprolactinaemia where surgery has already been used with incomplete resolution								
<u>Authority required (STREAMLINED)</u>								
2661								
Pathological hyperprolactinaemia where radiotherapy is not indicated								
<u>Authority required (STREAMLINED)</u>								
2662								
Pathological hyperprolactinaemia where radiotherapy has already been used with incomplete resolution								
8860H	quinagolide 25 microgram tablet [3 tablets] (&) quinagolide 50 microgram tablet [3 tablets], 6	1	..	..	11.81	12.96	Norprolac	FP
8822H	quinagolide 75 microgram tablet, 30	1	5	..	55.13	37.70	Norprolac	FP

SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM

HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE

Progestogens and estrogens, fixed combinations

ETHINYLLOESTRADIOL + LEVONORGESTREL								
1394J NP	ethinylloestradiol 30 microgram + levonorgestrel 150 microgram tablet [84] (&) inert substance tablet [28], 112 [4 x 28]	1	2	..	15.64	16.79	a Monofeme 28	FZ
							b Eleanor 150/30 ED	EA
							b Evelyn 150/30 ED	GQ
							b Femme-Tab ED 30/150	AE

GENITO URINARY SYSTEM AND SEX HORMONES

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							^b Levlen ED	SY
				^B 11.41	27.05	16.79	^b Micronelle 30 ED	TX
				^B 14.37	30.01	16.79	^b Microgynon 30 ED	BN
							^a Nordette 28	PF
1456P NP	ethinylloestradiol 50 microgram + levonorgestrel 125 microgram tablet [84] (&) inert substance tablet [28], 112 [4 x 28]	1	2	..	15.64	16.79	Microgynon 50 ED	BN
2416E NP	ethinylloestradiol 20 microgram + levonorgestrel 100 microgram tablet [84] (&) inert substance tablet [28], 112 [4 x 28]	1	2	..	15.64	16.79	Femme-Tab ED 20/100	AE
ETHINYLLOESTRADIOL + NORETHISTERONE								
2775C NP	ethinylloestradiol 35 microgram + norethisterone 1 mg tablet [84] (&) inert substance tablet [28], 112 [4 x 28]	1	2	..	16.80	17.95	^a Norimin-1 28 Day	FZ
				^B 10.67	27.47	17.95	^a Brevinor-1	PF
2774B NP	ethinylloestradiol 35 microgram + norethisterone 500 microgram tablet [84] (&) inert substance tablet [28], 112 [4 x 28]	1	2	..	16.80	17.95	^a Norimin 28 Day	FZ
				^B 10.67	27.47	17.95	^a Brevinor	PF
MESTRANOL + NORETHISTERONE								
3179H NP	mestranol 50 microgram + norethisterone 1 mg tablet [84] (&) inert substance tablet [28], 112 [4 x 28]	1	2	..	16.80	17.95	Norinyl-1/28	PF
Progestogens and estrogens, sequential preparations								
ETHINYLLOESTRADIOL + LEVONORGESTREL								
1392G NP	ethinylloestradiol 30 microgram + levonorgestrel 50 microgram tablet [24] (&) ethinylloestradiol 40 microgram + levonorgestrel 75 microgram tablet [20] (&) ethinylloestradiol 30 microgram + levonorgestrel 125 microgram tablet [40] (&) inert substance tablet [28], 112 [4 x 28]	1	2	..	15.64	16.79	^b Logynon ED	SY
				^B 11.41	27.05	16.79	^a Trifeme 28	FZ
				^B 14.37	30.01	16.79	^b Triquilar ED	BN
							^a Triphasil 28	PF
Progestogens								
ETONOGESTREL								
8487Q NP,MW	etonogestrel 68 mg implant, 1	1	..	..	216.26	37.70	Implanon NXT	MK
LEVONORGESTREL								
2913H NP,MW	levonorgestrel 30 microgram tablet, 112 [4 x 28 tablets]	1	2	..	17.66	18.81	Microlut 28	BN
MEDROXYPROGESTERONE								
3118D NP	medroxyprogesterone acetate 150 mg/mL injection, 1 x 1 mL vial	1	1	..	23.01	24.16	^a Depo-Ralovera	FZ
				^B 6.19	29.20	24.16	^a Depo-Provera	PF
NORETHISTERONE								
1967M NP	norethisterone 350 microgram tablet, 112 [4 x 28]	1	2	..	16.80	17.95	Micronor	JC
							Noriday 28 Day	PF

ANDROGENS

3-oxoandrosten (4) derivatives

TESTOSTERONE

GENITO URINARY SYSTEM AND SEX HORMONES

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	<u>Authority required</u>						
	Androgen deficiency						
	Clinical criteria:						
	Patient must have an established pituitary or testicular disorder.						
	Population criteria:						
	Patient must be male.						
	Treatment criteria:						
	Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.						
	The name of the specialist must be included in the authority application.						
	<u>Authority required</u>						
	Androgen deficiency						
	Clinical criteria:						
	Patient must not have an established pituitary or testicular disorder,						
	AND						
	The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.						
	Population criteria:						
	Patient must be male,						
	AND						
	Patient must be aged 40 years or older.						
	Treatment criteria:						
	Must be treated by a specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.						
	Androgen deficiency is defined as:						
	(i) testosterone level of less than 6 nmol per litre; OR						
	(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonadal reference range for young men, or greater than 14 IU per litre, whichever is higher).						
	Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.						
	The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.						
	The name of the specialist must be included in the authority application.						
	<u>Authority required</u>						
	Micropenis						
	Population criteria:						
	Patient must be male,						
	AND						
	Patient must be under 18 years of age.						
	Treatment criteria:						
	Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.						
	The name of the specialist must be included in the authority application.						
	<u>Authority required</u>						
	Pubertal induction						
	Population criteria:						
	Patient must be male,						
	AND						
	Patient must be under 18 years of age.						
	Treatment criteria:						
	Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.						

GENITO URINARY SYSTEM AND SEX HORMONES

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
The name of the specialist must be included in the authority application.								
<u>Authority required</u>								
Constitutional delay of growth or puberty								
Population criteria:								
Patient must be male,								
AND								
Patient must be under 18 years of age.								
Treatment criteria:								
Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.								
The name of the specialist must be included in the authority application.								
8830R	testosterone 1% (50 mg/5 g) gel, 30 x 5 g sachets	\$1	5	..	95.46	37.70	Testogel	HB
2341F	testosterone 2% (30 mg/1.5 mL actuation) transdermal solution, 60 actuations	\$1	5	..	82.79	37.70	Axiron	LY
8460G	testosterone 2.5 mg/24 hours patch, 60	\$1	5	..	96.18	37.70	Androderm	GN
8619P	testosterone 5 mg/24 hours patch, 30	\$1	5	..	96.18	37.70	Androderm	GN

TESTOSTERONE ENANTHATE

Authority required

Androgen deficiency

Clinical criteria:

Patient must have an established pituitary or testicular disorder.

Population criteria:

Patient must be male.

Treatment criteria:

Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

Authority required

Androgen deficiency

Clinical criteria:

Patient must not have an established pituitary or testicular disorder,

AND

The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

Population criteria:

Patient must be male,

AND

Patient must be aged 40 years or older.

Treatment criteria:

Must be treated by a specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Androgen deficiency is defined as:

(i) testosterone level of less than 6 nmol per litre; OR

(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonadal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

The name of the specialist must be included in the authority application.

TESTOSTERONE UNDECANOATE

Authority required

Androgen deficiency

Clinical criteria:

Patient must have an established pituitary or testicular disorder.

Population criteria:

Patient must be male.

Treatment criteria:

Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

Authority required

Androgen deficiency

Clinical criteria:

Patient must not have an established pituitary or testicular disorder.

AND

The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

GENITO URINARY SYSTEM AND SEX HORMONES

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	Population criteria: Patient must be male, AND Patient must be aged 40 years or older. Treatment criteria: Must be treated by a specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists. Androgen deficiency is defined as: (i) testosterone level of less than 6 nmol per litre; OR (ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonadal reference range for young men, or greater than 14 IU per litre, whichever is higher). Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings. The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated. The name of the specialist must be included in the authority application. Authority required Micropenis						
	Population criteria: Patient must be male, AND Patient must be under 18 years of age. Treatment criteria: Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists. The name of the specialist must be included in the authority application. Authority required Pubertal induction						
	Population criteria: Patient must be male, AND Patient must be under 18 years of age. Treatment criteria: Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists. The name of the specialist must be included in the authority application. Authority required Constitutional delay of growth or puberty						
	Population criteria: Patient must be male, AND Patient must be under 18 years of age. Treatment criteria: Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists. The name of the specialist must be included in the authority application.						
10205D	testosterone undecanoate 1 g/4 mL injection, 1 x 4 mL vial	1	1	..	147.75	37.70	Reandron 1000 BN
2115H	testosterone undecanoate 40 mg capsule, 60	1	5	..	37.87	37.70	Andriol Testocaps MK

ESTROGENS

Natural and semisynthetic estrogens, plain

GENITO URINARY SYSTEM AND SEX HORMONES

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
OESTRADIOL								
Note								
Oestradiol should be used in conjunction with an oral progestogen in women with an intact uterus.								
Note								
Continuing Therapy Only:								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8286D NP	oestradiol 0.1% (1 mg/g) gel, 28 x 1 g sachets	‡1	5	..	17.43	18.58	Sandrena	AS
8126Q NP	oestradiol 100 microgram/24 hours patch, 4	‡1	5	..	19.47	20.62	Climara 100	BN
8312L NP	oestradiol 100 microgram/24 hours patch, 8	‡1	5	..	19.47	20.62	Estraderm MX 100	NV
8765H NP	oestradiol 100 microgram/24 hours patch, 8	‡1	5	..	19.47	20.62	Estradot 100	NV
8485N NP	oestradiol 25 microgram/24 hours patch, 4	‡1	5	..	17.43	18.58	Climara 25	BN
8311K NP	oestradiol 25 microgram/24 hours patch, 8	‡1	5	..	17.43	18.58	Estraderm MX 25	NV
8761D NP	oestradiol 25 microgram/24 hours patch, 8	‡1	5	..	17.43	18.58	Estradot 25	NV
8762E NP	oestradiol 37.5 microgram/24 hours patch, 8	‡1	5	..	17.43	18.58	Estradot 37.5	NV
8125P NP	oestradiol 50 microgram/24 hours patch, 4	‡1	5	..	17.43	18.58	Climara 50	BN
8140K NP	oestradiol 50 microgram/24 hours patch, 8	‡1	5	..	17.43	18.58	Estraderm MX 50	NV
8763F NP	oestradiol 50 microgram/24 hours patch, 8	‡1	5	..	17.43	18.58	Estradot 50	NV
8486P NP	oestradiol 75 microgram/24 hours patch, 4	‡1	5	..	19.47	20.62	Climara 75	BN
8764G NP	oestradiol 75 microgram/24 hours patch, 8	‡1	5	..	19.47	20.62	Estradot 75	NV
OESTRADIOL								
Note								
Continuing Therapy Only:								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
10203B NP	oestradiol 10 microgram pessary: modified release, 18	1	2	..	31.20	32.35	Vagifem Low	NO
OESTRADIOL								
Note								
Continuing Therapy Only:								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8274L NP	oestradiol 2 mg tablet, 56	1	2	..	13.89	15.04	Zumenon	GO
1663M NP	oestradiol valerate 1 mg tablet, 56	1	2	..	12.02	13.17	Progynova	BN
1664N NP	oestradiol valerate 2 mg tablet, 56	1	2	..	14.24	15.39	Progynova	BN
OESTRIOL								
Note								
Continuing Therapy Only:								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
1781R NP	oestriol 0.1% (1 mg/g) cream, 15 g	‡1	1	..	19.43	20.58	Ovestin	AS
1771F NP	oestriol 500 microgram pessary, 15	‡1	2	..	21.60	22.75	Ovestin Ovula	AS

PROGESTOGENS

Pregnen (4) derivatives

GENITO URINARY SYSTEM AND SEX HORMONES

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
MEDROXYPROGESTERONE								
<u>Restricted benefit</u>								
Endometriosis								
2722G	medroxyprogesterone acetate 10 mg tablet, 100	1	2	..	33.10	34.25	^a Ralovera	FZ
				^b 2.53	35.63	34.25	^a Provera	PF
MEDROXYPROGESTERONE								
<u>Note</u>								
Continuing Therapy Only:								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
2321E NP	medroxyprogesterone acetate 10 mg tablet, 30	1	2	..	14.66	15.81	^a Ralovera	FZ
				^b 2.46	17.12	15.81	^a Provera	PF
2323G NP	medroxyprogesterone acetate 5 mg tablet, 56	1	2	..	15.96	17.11	^a Ralovera	FZ
				^b 2.59	18.55	17.11	^a Provera	PF

Estren derivatives

NORETHISTERONE

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2993M NP	norethisterone 5 mg tablet, 30	1	2	..	32.30	33.45	Primolut N	BN

PROGESTOGENS AND ESTROGENS IN COMBINATION

Progestogens and estrogens, fixed combinations

NORETHISTERONE ACETATE + OESTRADIOL

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8427M NP	oestradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch, 8	1	5	..	19.47	20.62	Estalis continuous 50/140	NV
8428N NP	oestradiol 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch, 8	1	5	..	19.47	20.62	Estalis continuous 50/250	NV

OESTRADIOL + DYDROGESTERONE

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

10142T NP	oestradiol 1 mg + dydrogesterone 5 mg tablet, 28	1	5	..	19.10	20.25	Femoston-Conti	GO

Progestogens and estrogens, sequential preparations

NORETHISTERONE ACETATE + OESTRADIOL (&) OESTRADIOL

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8425K NP	oestradiol 50 microgram/24 hours patch [4 patches] (&) oestradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch [4 patches], 8	1	5	..	19.47	20.62	Estalis sequi 50/140	NV
8426L NP	oestradiol 50 microgram/24 hours patch [4 patches] (&) oestradiol 50	1	5	..	19.47	20.62	Estalis sequi 50/250	NV

GENITO URINARY SYSTEM AND SEX HORMONES

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch [4 patches], 8						

OESTRADIOL (&) OESTRADIOL + DYDROGESTERONE

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

10146B NP	oestradiol 1 mg tablet [14] (& oestradiol 1 mg + dydrogesterone 10 mg tablet [14], 28	\$1	5	..	19.10	20.25	Femoston 1/10	GO

OESTRADIOL (&) OESTRADIOL + DYDROGESTERONE

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8244X NP	oestradiol 2 mg tablet [14] (& oestradiol 2 mg + dydrogesterone 10 mg tablet [14], 28	\$1	5	..	19.10	20.25	Femoston 2/10	GO

GONADOTROPINS AND OTHER OVULATION STIMULANTS

Gonadotropins

FOLLITROPIN ALFA

Restricted benefit

Anovulatory infertility

Restricted benefit

For the treatment of infertility in males due to hypogonadotrophic hypogonadism, following failure of 6 months' treatment with human chorionic gonadotrophin to achieve adequate spermatogenesis. Combined treatment with HCG must be given

Note

Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomiphene citrate and/or gonadorelin and failed to have conceived.

Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.

Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

8713N	follitropin alfa 300 international units / 0.5 mL (21.84 microgram/0.5 mL) injection, 1 x 0.5 mL cartridge	3	5	..	*493.84	37.70	Gonal-f Pen	SG
8714P	follitropin alfa 450 international units / 0.75 mL (32.76 microgram/0.75 mL) injection, 1 x 0.75 mL cartridge	3	5	..	*737.41	37.70	Gonal-f Pen	SG
8715Q	follitropin alfa 900 international units / 1.5 mL (65.52 microgram/1.5 mL) injection, 1 x 1.5 mL cartridge	2	5	..	*980.94	37.70	Gonal-f Pen	SG

FOLLITROPIN BETA

Restricted benefit

Anovulatory infertility

Restricted benefit

For the treatment of infertility in males due to hypogonadotrophic hypogonadism, following failure of 6 months' treatment with human chorionic gonadotrophin to achieve adequate spermatogenesis. Combined treatment with HCG must be given

Note

Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomiphene citrate and/or gonadorelin and failed to have conceived.

Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.

Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

8565T	follitropin beta 300 international units/0.36 mL injection, 1 x 0.36 mL	3	5	..	*509.95	37.70	Puregon 300 IU/0.36 mL	MK

GENITO URINARY SYSTEM AND SEX HORMONES

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
8566W	cartridge follitropin beta 600 international units/0.72 mL injection, 1 x 0.72 mL	2	5	..	*661.40	37.70	Puregon 600 IU/0.72 mL	MK
8871X	cartridge follitropin beta 900 international units/1.08 mL injection, 1 x 1.08 mL	2	5	..	*979.92	37.70	Puregon 900 IU/1.08 mL	MK
GONADOTROPHIN CHORIONIC HUMAN								
<u>Restricted benefit</u> Anovulatory infertility								
<u>Restricted benefit</u> For the treatment of infertility in males due to hypogonadotrophic hypogonadism								
<u>Restricted benefit</u> For the treatment of infertility in males associated with isolated luteinising hormone deficiency								
<u>Restricted benefit</u> For the treatment of males who have combined deficiency of human growth hormone and gonadotrophins and in whom the absence of secondary sexual characteristics indicates a lag in maturation								
<u>Restricted benefit</u> For the treatment of boys over the age of 16 years who show clinical evidence of hypogonadism or delayed puberty. Treatment must not extend beyond 6 months								
<u>Note</u> Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomiphene citrate and/or gonadorelin and failed to have conceived. Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception. Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment. Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.								
1581F	gonadotrophin chorionic human 1500 international units injection [3 x 1500 international units ampoules] (& inert substance diluent [3 x 1 mL ampoules], 1 pack	1	5	..	53.81	37.70	Pregnyl	MK
<i>Ovulation stimulants, synthetic</i>								
CLOMIPHENE								
<u>Restricted benefit</u> Anovulatory infertility								
<u>Restricted benefit</u> Patients undergoing in-vitro fertilisation								
<u>Note</u> Care must be taken to comply with the provisions of State/Territory law when prescribing clomiphene citrate.								
1211R	clomiphene citrate 50 mg tablet, 10	1	5	..	34.85	36.00	^a Clomid	SW
							^a Serophene	SG
ANTIANDROGENS								
<i>Antiandrogens, plain</i>								
CYPROTERONE								
<u>Authority required (STREAMLINED)</u> 1014 Advanced carcinoma of the prostate								
<u>Authority required (STREAMLINED)</u> 1404 To reduce drive in sexual deviations in males								
8019C	cyproterone acetate 100 mg tablet, 50	1	5	..	85.11	37.70	^a Cyprocur 100	QA
							^a Cyprostat-100	SY
							^a Cyproterone AN	EA
							^a Cyproterone Sandoz	HX
							^a GenRx Cyproterone Acetate	GX

GENITO URINARY SYSTEM AND SEX HORMONES

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer		
1270W	cyproterone acetate 50 mg tablet, 50	2	5	B0.80 ..	85.91 *107.36	37.70 37.70	a	Procur 100	GN
							a	Androcur-100	BN
							a	Cyprocur 50	QA
				a	Cyprone	AF			
				a	Cyprostat	SY			
				a	Cyproterone AN	EA			
				a	Cyproterone Sandoz	HX			
				a	Cyrotone	ER			
				a	GenRx Cyproterone Acetate	GX			
				a	Procur	GN			
B1.88	*109.24	37.70	a	Androcur	BN				

CYPROTERONE

Authority required (STREAMLINED)

1230

Moderate to severe androgenisation in non-pregnant women (acne alone is not a sufficient indication of androgenisation)

Caution

This drug should not be used during pregnancy as it may result in feminisation of the male foetus.

1269T	cyproterone acetate 50 mg tablet, 20	1	5	..	27.79	28.94	^a Cyprocur 50	QA
							^a Cyprone	AF
							^a Cyprostat	SY
							^a Cyproterone AN	EA
							^a Cyproterone Sandoz	HX
							^a GenRx Cyproterone Acetate	GX
							^a Procur	GN
				^B 2.05	29.84	28.94	^a Androcur	BN

OTHER SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM

Antigonadotropins and similar agents

DANAZOL

Authority required (STREAMLINED)

1090

Endometriosis, visually proven

Authority required (STREAMLINED)

1151

Hereditary angio-oedema

Authority required (STREAMLINED)

2639

Short-term treatment (up to 6 months) of intractable primary menorrhagia (Treatment of this indication is limited to 6 months. See Australian Product Information)

Authority required (STREAMLINED)

2640

Short-term treatment (up to 6 months) of severe benign (fibrocystic) breast disease or mastalgia associated with severe symptomatic benign breast disease in patients refractory to other treatments (Treatment of this indication is limited to 6 months. See Australian Product Information)

Caution

Pregnancy must be excluded prior to administration of this drug.

1285P	danazol 100 mg capsule, 100	1	5	..	58.92	37.70	Azol 100	AF
1287R	danazol 200 mg capsule, 100	1	5	..	87.31	37.70	Azol 200	AF

GESTRINONE

Authority required (STREAMLINED)

3652

Short-term treatment (up to 6 months) of visually proven endometriosis (only 1 course of not more than 6 months' therapy may be prescribed)

8015W	gestrinone 2.5 mg capsule, 8	1	5	..	82.15	37.70	Dimetriose	SW

Antiprogestogens

GENITO URINARY SYSTEM AND SEX HORMONES

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
MIFEPRISTONE (&) MISOPROSTOL								
<u>Authority required</u>								
Termination of an intra-uterine pregnancy								
<u>Clinical criteria:</u>								
The condition must be an intra-uterine pregnancy of up to 63 days of gestation.								
<u>Treatment criteria:</u>								
Must be treated by a prescriber who is registered with the MS 2 Step Prescribing Program.								
<u>Note</u>								
No increase in the maximum quantity or number of units may be authorised.								
<u>Note</u>								
No increase in the maximum number of repeats may be authorised.								
10211K	mifepristone 200 mg tablet [1] (&) misoprostol 200 microgram tablet [4], 1 pack	1	..	..	321.38	37.70	MS-2 Step	XH

UROLOGICALS

UROLOGICALS

Drugs for urinary frequency and incontinence

OXYBUTYNIN

Restricted benefit

Detrusor overactivity in a patient who cannot tolerate oral oxybutynin, or who cannot swallow oral oxybutynin

9454N NP	oxybutynin 3.9 mg/24 hours patch, 8	1	5	..	35.57	36.72	Oxytrol	GN

OXYBUTYNIN

Restricted benefit

Detrusor overactivity

8039D NP	oxybutynin hydrochloride 5 mg tablet, 100	1	5	..	13.80	14.95	^a Ditropan	SW
							^a Oxybutynin Sandoz	SZ
							^a Oxybutynin Winthrop	WA

PROPANTHELINE

Restricted benefit

Detrusor overactivity

1953T NP	propantheline bromide 15 mg tablet, 100	2	5	..	*26.80	27.95	Pro-Banthine	QA

Other urologicals

BICARBONATE

9470K NP	sodium bicarbonate 840 mg capsule, 100	1	2	..	14.34	15.49	Sodibic	AS

PHENOXYBENZAMINE

Authority required

Phaeochromocytoma

Authority required

Neurogenic urinary retention

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1862B NP	phenoxybenzamine hydrochloride 10 mg capsule, 100	1	5	..	1164.81	37.70	Dibenylene	GH
9286R NP	phenoxybenzamine hydrochloride 10 mg capsule, 100	1	5	..	6860.58	37.70	Dibenzyline	BZ
1166J NP	phenoxybenzamine hydrochloride 10 mg capsule, 30	3	5	..	*205.24	37.70	Dibenylene	GH

GENITO URINARY SYSTEM AND SEX HORMONES

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY

Alpha-adrenoreceptor antagonists

DUTASTERIDE + TAMSULOSIN

Authority required (STREAMLINED)

3687

Treatment of lower urinary tract symptoms due to benign prostatic hyperplasia where treatment has been initiated by a urologist

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

5490Y NP	dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram capsule: modified release, 30	1	5	..	35.63	36.78	Duodart 500ug/400ug	GK

Testosterone-5-alpha reductase inhibitors

DUTASTERIDE

Authority required (STREAMLINED)

3667

Treatment, in combination with an alpha-antagonist, of lower urinary tract symptoms due to benign prostatic hyperplasia where treatment is initiated by a urologist

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

5468T NP	dutasteride 500 microgram capsule, 30	1	5	..	30.77	31.92	Avodart	GK

SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES

ACTH

TETRACOSACTRIN

2832C	tetracosactrin 1 mg/mL injection: modified release, 1 x 1 mL ampoule	5	5	..	*71.61	37.70	Synacthen Depot 1 mg/1 mL	NV

Thyrotropin

THYROTROPIN ALFA

Authority required (STREAMLINED)

3193

Ablation of thyroid remnant tissue, in combination with radioactive iodine, in a post thyroidectomy patient without known metastatic disease

2700D	thyrotropin alfa 900 microgram injection, 2 x 900 microgram vials	1	..	..	1901.76	37.70	Thyrogen	GZ

POSTERIOR PITUITARY LOBE HORMONES

Vasopressin and analogues

DESMOPRESSIN

Authority required (STREAMLINED)

2641

Primary nocturnal enuresis in patients aged 6 years or older who are refractory to an enuresis alarm

Authority required (STREAMLINED)

2642

Primary nocturnal enuresis in patients aged 6 years or older for whom an enuresis alarm is contraindicated. The reason that an alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

Note

Not to be used in preference to enuresis alarms.

Desmopressin nasal spray may be associated with an increased risk of hyponatraemia compared to the oral formulations.

Note

Only one application per six months will be authorised for the wafers. No more than twice the maximum quantity for the 120 micrograms wafers and no applications for increased maximum quantities for the 240 micrograms wafers will be authorised.

9398P NP	desmopressin 120 microgram wafer: sublingual, 30	1	5	..	71.19	37.70	Minirin Melt	FP
8975J NP	desmopressin 240 microgram wafer: sublingual, 30	1	5	..	116.28	37.70	Minirin Melt	FP

DESMOPRESSIN

Authority required (STREAMLINED)

1678

Cranial diabetes insipidus

8711L	desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations	2	5	..	*161.38	37.70	Minirin Nasal Spray	FP
2129C	desmopressin acetate 100 microgram/mL nasal drops, 2.5 mL	5	5	..	*161.51	37.70	Minirin	FP
8662X	desmopressin acetate 200 microgram tablet, 30	3	5	..	*180.25	37.70	Minirin	FP

DESMOPRESSIN

Authority required (STREAMLINED)

2641

Primary nocturnal enuresis in patients aged 6 years or older who are refractory to an enuresis alarm

Authority required (STREAMLINED)

2642

Primary nocturnal enuresis in patients aged 6 years or older for whom an enuresis alarm is contraindicated. The reason that an alarm is

SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	contraindicated must be documented in the patient's medical records when treatment is initiated							
	Note							
	Not to be used in preference to enuresis alarms.							
	Desmopressin nasal spray may be associated with an increased risk of hyponatraemia compared to the oral formulations.							
8712M NP	desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations	‡1	5	..	84.07	37.70	Minirin Nasal Spray	FP
	DESMOPRESSIN							
	Authority required (STREAMLINED)							
	2641							
	Primary nocturnal enuresis in patients aged 6 years or older who are refractory to an enuresis alarm							
	Authority required (STREAMLINED)							
	2642							
	Primary nocturnal enuresis in patients aged 6 years or older for whom an enuresis alarm is contraindicated. The reason that an alarm is contraindicated must be documented in the patient's medical records when treatment is initiated							
	Note							
	Not to be used in preference to enuresis alarms.							
	Desmopressin nasal spray may be associated with an increased risk of hyponatraemia compared to the oral formulations.							
	Note							
	Only one application per six months with no more than twice the maximum quantity will be authorised for the tablets.							
8663Y NP	desmopressin acetate 200 microgram tablet, 30	1	5	..	64.59	37.70	Minirin	FP

HYPOTHALAMIC HORMONES

Gonadotropin-releasing hormones

NAFARELIN

Authority required

Initial treatment (up to 6 months) of visually proven endometriosis

Authority required

Subsequent treatment (up to 6 months) of visually proven endometriosis, where 2 years or more have elapsed since the end of the previous course and where a recent bone density assessment has been made. The date of the assessment must be provided

2962X	nafarelin 200 microgram/actuation nasal spray, 60 actuations	‡1	5	..	132.13	37.70	Synarel	PF

CORTICOSTEROIDS FOR SYSTEMIC USE

CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN

Mineralocorticoids

FLUDROCORTISONE ACETATE

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1433K NP	fludrocortisone acetate 100 microgram tablet, 100	2	1	..	*46.84	37.70	Florinef	QA

Glucocorticoids

BETAMETHASONE ACETATE + BETAMETHASONE SODIUM PHOSPHATE

Restricted benefit

Alopecia areata

Restricted benefit

For local intra-articular or peri-articular infiltration

Restricted benefit

Granulomata, dermal

Restricted benefit

Keloid

Restricted benefit

Lichen planus hypertrophic

SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	<u>Restricted benefit</u> Lichen simplex chronicus							
	<u>Restricted benefit</u> Lupus erythematosus, chronic discoid							
	<u>Restricted benefit</u> Necrobiosis lipoidica							
	<u>Restricted benefit</u> Uveitis							
	<u>Note</u> Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
2694T NP	betamethasone (as acetate) 2.71 mg/mL + betamethasone (as sodium phosphate) 2.96 mg/mL injection, 5 x 1 mL ampoules	1	..	..	25.34	26.49	Celestone Chronodose	MK
	BETAMETHASONE ACETATE + BETAMETHASONE SODIUM PHOSPHATE							
	<u>Restricted benefit</u> For local intra-articular or peri-articular infiltration							
	<u>Restricted benefit</u> Keloid							
	<u>Restricted benefit</u> Lichen planus hypertrophic							
5034Y DP	betamethasone (as acetate) 2.71 mg/mL + betamethasone (as sodium phosphate) 2.96 mg/mL injection, 5 x 1 mL ampoules	1	..	..	25.34	26.49	Celestone Chronodose	MK
	CORTISONE							
	<u>Note</u> Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
1247P NP	cortisone acetate 25 mg tablet, 60	1	4	..	18.08	19.23	Cortate	AS
1246N NP	cortisone acetate 5 mg tablet, 50	1	4	..	15.64	16.79	Cortate	AS
	DEXAMETHASONE							
	<u>Note</u> Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
2507Y NP	DEXAMETHASONE Tablet 4 mg, 30	1	4	..	12.74	13.89	Dexamethsone	AS
1292B NP	DEXAMETHASONE Tablet 500 micrograms, 30	1	4	..	9.18	10.33	Dexamethsone	AS
	DEXAMETHASONE SODIUM PHOSPHATE							
	<u>Note</u> Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
2509C NP	DEXAMETHASONE SODIUM PHOSPHATE Injection equivalent to 4 mg dexamethasone phosphate in 1 mL, 5	1	..	..	17.96	19.11 ^a	Dexamethsone	AF
1291Y NP	DEXAMETHASONE SODIUM PHOSPHATE Injection equivalent to 8 mg dexamethasone phosphate in 2 mL, 5	1	1	..	25.28	26.43 ^a	Hospira Pty Limited Dexamethsone	HH AF

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							^a Hospira Pty Limited	HH
HYDROCORTISONE								
Note								
Continuing Therapy Only:								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
1500Y NP	hydrocortisone 20 mg tablet, 60	1	4	..	30.50	31.65	Hysone 20	AF
1499X NP	hydrocortisone 4 mg tablet, 50	1	4	..	23.39	24.54	Hysone 4	AF
HYDROCORTISONE SODIUM SUCCINATE								
1501B NP	hydrocortisone (as sodium succinate) 100 mg injection [1 x 100 mg vial] (&) inert substance diluent [1 x 2 mL vial], 1 pack	2	..	..	*18.04	19.19	Solu-Cortef	PF
3096Y NP	hydrocortisone (as sodium succinate) 250 mg injection [1 x 250 mg vial] (&) inert substance diluent [1 x 2 mL vial], 1 pack	1	..	..	16.83	17.98	Solu-Cortef	PF
HYDROCORTISONE SODIUM SUCCINATE								
Restricted benefit								
For use in a hospital								
1510L NP	hydrocortisone (as sodium succinate) 100 mg injection [1 x 100 mg vial] (&) inert substance diluent [1 x 2 mL vial], 1 pack	6	..	..	*40.60	37.70	Solu-Cortef	PF
5118J DP	hydrocortisone (as sodium succinate) 100 mg injection [1 x 100 mg vial] (&) inert substance diluent [1 x 2 mL vial], 1 pack	6	..	..	*40.60	37.70	Solu-Cortef	PF
1511M NP	hydrocortisone (as sodium succinate) 250 mg injection [1 x 250 mg vial] (&) inert substance diluent [1 x 2 mL vial], 1 pack	6	..	..	*64.60	37.70	Solu-Cortef	PF
5119K DP	hydrocortisone (as sodium succinate) 250 mg injection [1 x 250 mg vial] (&) inert substance diluent [1 x 2 mL vial], 1 pack	6	..	..	*64.60	37.70	Solu-Cortef	PF
METHYLPREDNISOLONE								
Note								
Pharmaceutical benefits that have the form methylprednisolone powder for injection 1 g (as sodium succinate) and pharmaceutical benefits that have the form methylprednisolone powder for injection 1 g (as sodium succinate) with diluent are equivalent for the purposes of substitution.								
8834Y NP	methylprednisolone 1 g injection [1 x 1 g vial] (&) inert substance diluent [1 x 16 mL vial], 1 pack	1	..	..	55.68	37.70	^a Solu-Medrol	PF
5264C NP	methylprednisolone Powder for injection 1 g (as sodium succinate), 1	1	..	..	55.68	37.70	^a Methylpred	AL
							^a Methylprednisolone Alphapharm	AF
METHYLPREDNISOLONE								
Note								
Pharmaceutical benefits that have the form methylprednisolone powder for injection 40 mg (as sodium succinate) and pharmaceutical benefits that have the form methylprednisolone powder for injection 40 mg (as sodium succinate) with diluent are equivalent for the purposes of substitution.								
2981X NP	methylprednisolone 40 mg injection [5 x 40 mg vials] (&) inert substance diluent [5 x 1 mL vials], 1 pack	1	..	..	22.80	23.95	^a Solu-Medrol	PF
5263B NP	methylprednisolone Powder for injection 40 mg (as sodium succinate), 5	1	..	..	22.80	23.95	^a Methylpred	AL
METHYLPREDNISOLONE								
Restricted benefit								
For local intra-articular or peri-articular infiltration								

SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
1928L NP	methylprednisolone acetate 40 mg/mL injection, 5 x 1 mL vials	1	..	..	19.42	20.57	^a Depo-Nisolone	FZ
				^B 1.08	20.50	20.57	^a Depo-Medrol	PF
5148Y DP	methylprednisolone acetate 40 mg/mL injection, 5 x 1 mL vials	1	..	..	19.42	20.57	^a Depo-Nisolone	FZ
				^B 1.08	20.50	20.57	^a Depo-Medrol	PF
PREDNISOLONE								
3152X NP	prednisolone 1 mg tablet, 100	1	4	..	8.67	9.82	^a Predsolone	LN
				^B 0.82	9.49	9.82	^a Panafcortelone	AS
1916W NP	prednisolone 25 mg tablet, 30	1	4	..	10.47	11.62	Panafcortelone	AS
1917X NP	prednisolone 5 mg tablet, 60	1	4	..	8.81	9.96	Solone Panafcortelone	IA AS
							Solone	IA
PREDNISOLONE SODIUM PHOSPHATE								
8285C NP	prednisolone (as sodium phosphate) 5 mg/mL oral liquid, 30 mL	1	5	..	15.04	16.19	^a PredMix	LN
				^B 2.70	17.74	16.19	^a Redipred	AS
PREDNISONE								
1934T NP	prednisone 1 mg tablet, 100	1	4	..	9.20	10.35	^a Predsone	LN
				^B 0.91	10.11	10.35	^a Panafcort	AS
1936X NP	prednisone 25 mg tablet, 30	1	4	..	11.75	12.90	Panafcort	AS
1935W NP	prednisone 5 mg tablet, 60	1	4	..	9.52	10.67	Sone Panafcort	IA AS
							Sone	IA
TRIAMCINOLONE								
<u>Restricted benefit</u>								
Alopecia areata								
<u>Restricted benefit</u>								
For local intra-articular or peri-articular infiltration								
<u>Restricted benefit</u>								
Granulomata, dermal								
<u>Restricted benefit</u>								
Keloid								
<u>Restricted benefit</u>								
Lichen planus hypertrophic								
<u>Restricted benefit</u>								
Lichen simplex chronicus								
<u>Restricted benefit</u>								
Lupus erythematosus, chronic discoid								
<u>Restricted benefit</u>								
Necrobiosis lipoidica								
<u>Restricted benefit</u>								
Psoriasis								
<u>Note</u>								
Shared Care Model:								
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
2990J NP	triamcinolone acetonide 10 mg/mL injection, 5 x 1 mL ampoules	1	..	..	25.34	26.49	Kenacort-A10	QA

TRIAMCINOLONE

Restricted benefit

For local intra-articular or peri-articular infiltration

SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Restricted benefit Keloid							
	Restricted benefit Lichen planus hypertrophic							
5233K DP	triamcinolone acetonide 10 mg/mL injection, 5 x 1 mL ampoules	1	..	..	25.34	26.49	Kenacort-A10	QA

THYROID THERAPY

THYROID PREPARATIONS

Thyroid hormones

LIOTHYRONINE

Authority required (STREAMLINED)

1219

Management of patients with thyroid cancer

Authority required (STREAMLINED)

1858

Replacement therapy for hypothyroid patients who have documented intolerance to thyroxine sodium

Authority required (STREAMLINED)

1859

Replacement therapy for hypothyroid patients who have documented resistance to thyroxine sodium

Authority required (STREAMLINED)

1182

Initiation of thyroid therapy in severely hypothyroid patients

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2318B NP	liothyronine sodium 20 microgram tablet, 100	1	2	..	83.87	37.70	Tertroxin	QA

THYROXINE

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2175L NP	thyroxine sodium 100 microgram tablet, 200	1	1	..	24.32	25.47	^a Eutroxsig	FM
				^b 2.21	26.53	25.47	^a Oroxine	QA
2173J NP	thyroxine sodium 200 microgram tablet, 200	1	1	..	27.35	28.50	^a Eutroxsig	FM
				^b 2.21	29.56	28.50	^a Oroxine	QA
2174K NP	thyroxine sodium 50 microgram tablet, 200	1	1	..	23.71	24.86	^a Eutroxsig	FM
				^b 2.20	25.91	24.86	^a Oroxine	QA
9287T NP	thyroxine sodium 75 microgram tablet, 200	1	1	..	24.36	25.51	^a Eutroxsig	FM
				^b 2.27	26.63	25.51	^a Oroxine	QA

ANTITHYROID PREPARATIONS

Thiouracils

PROPYLTHIOURACIL

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1955X NP	propylthiouracil 50 mg tablet, 100	2	2	..	*49.98	37.70	PTU	PL

Sulfur-containing imidazole derivatives

CARBIMAZOLE

Note

SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
Continuing Therapy Only:								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
1153Q NP	carbamazole 5 mg tablet, 100	2	2	..	*31.38	32.53	Carbimazol ARISTO	PQ
							Neo-Mercazole	LM

PANCREATIC HORMONES

GLYCOGENOLYTIC HORMONES

Glycogenolytic hormones

GLUCAGON HYDROCHLORIDE

1449G NP	glucagon hydrochloride 1 mg injection [1 x 1 mg vial] (&) inert substance diluent [1 x 1 mL syringe], 1 pack	1	1	..	50.55	37.70	GlucaGen Hypokit	NO
5105Q DP	glucagon hydrochloride 1 mg injection [1 x 1 mg vial] (&) inert substance diluent [1 x 1 mL syringe], 1 pack	1	..	..	50.55	37.70	GlucaGen Hypokit	NO

CALCIUM HOMEOSTASIS

PARATHYROID HORMONES AND ANALOGUES

Parathyroid hormones and analogues

TERIPARATIDE

Authority required

Severe established osteoporosis

Treatment Phase: Initial treatment

Clinical criteria:

Patient must be at very high risk of fracture,

AND

Patient must have a bone mineral density (BMD) T-score of -3.0 or less,

AND

Patient must have had 2 or more fractures due to minimal trauma,

AND

Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses,

AND

The treatment must be the sole PBS-subsidised agent,

AND

The treatment must not exceed a lifetime maximum of 18 months therapy.

Treatment criteria:

Must be treated by a specialist; OR

Must be treated by a consultant physician.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months, strontium ranelate 2 g per day and zoledronic acid 5 mg per annum.

Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be provided at the time of application.

SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	<u>Note</u> Details of accepted toxicities including severity can be found on the Department of Human Services website at www.humanservices.gov.au. <u>Note</u> No increase in the maximum quantity or number of units may be authorised. <u>Note</u> No increase in the maximum number of repeats may be authorised. <u>Note</u> Special Pricing Arrangements apply. <u>Authority required</u> Severe established osteoporosis Treatment Phase: Continuing treatment <u>Clinical criteria:</u> Patient must have previously been issued with an authority prescription for this drug, AND The treatment must not exceed a lifetime maximum of 18 months therapy. <u>Note</u> Up to a maximum of 18 pens will be reimbursed through the PBS. <u>Note</u> No increase in the maximum quantity or number of units may be authorised. <u>Note</u> No increase in the maximum number of repeats may be authorised. <u>Note</u> Special Pricing Arrangements apply.						
9411H	teriparatide 20 microgram/dose injection, 1 x 2.4 mL cartridge	1	5	..	438.71	37.70	Forteo

LY

ANTI-PARATHYROID AGENTS

Calcitonin preparations

SALCATONIN

Authority required (STREAMLINED)

3256

Symptomatic Paget disease of bone

Authority required (STREAMLINED)

1412

Treatment initiated in a hospital (in-patient or out-patient) of hypercalcaemia

Note

The maximum quantities for salcatonin shown represent the number of individual ampoules and NOT multiples of the manufacturer's packs. The pack size for both strengths is five ampoules.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2997R NP	salcatonin 100 international units/mL injection, 5 x 1 mL ampoules	3	5	..	*161.47	37.70	Miacalcic 100	NV

Other anti-parathyroid agents

CINACALCET

Authority required (STREAMLINED)

3673

Maintenance therapy, following initiation and stabilisation of treatment with cinacalcet, of a patient with chronic kidney disease on dialysis who has a decrease of at least 30% in iPTH concentrations after 6 months treatment

Authority required (STREAMLINED)

3672

Maintenance therapy, following initiation and stabilisation of treatment with cinacalcet, of a patient with chronic kidney disease on dialysis who has iPTH greater than 15 pmol per L and an (adjusted) serum calcium concentration of less than 2.6 mmol per L after 6 months treatment

Note

During the titration phase, intact PTH should be monitored 4 weekly (measured at least 12 hours post dose) and dose titrated until an appropriate iPTH concentration is achieved. During the titration phase, approval will be limited to sufficient supply for 4 weeks treatment at a time, with doses

SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	between 30 and 180 mg per day according to the patient's response and tolerability.							
	During the maintenance phase, approval will be limited to provide sufficient quantity for 4 weeks treatment up to a maximum of 6 months supply for doses between 30 and 180 mg per day according to the patient's response and tolerability. Intact PTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.							
	Note							
	Special Pricing Arrangements apply.							
	Note							
	Shared Care Model:							
	For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
9157Y NP	cinacalcet 30 mg tablet, 28	1	5	..	232.23	37.70	Sensipar	AN
9158B NP	cinacalcet 60 mg tablet, 28	1	5	..	439.70	37.70	Sensipar	AN
9159C NP	cinacalcet 90 mg tablet, 28	1	5	..	654.07	37.70	Sensipar	AN

ANTIINFECTIVES FOR SYSTEMIC USE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

ANTIINFECTIVES FOR SYSTEMIC USE

ANTIBACTERIALS FOR SYSTEMIC USE

TETRACYCLINES

Tetracyclines

DOXYCYCLINE

Restricted benefit

Urethritis

Note

Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hydrochloride), doxycycline tablet 100 mg (as monohydrate) and doxycycline capsule: modified release 100 mg (as hydrochloride) are equivalent for the purposes of substitution.

2715X NP	doxycycline 100 mg capsule: modified release, 21 capsules	1	..	^B 1.93	11.96	11.18	^a	Mayne Pharma Doxycycline	YT
				^B 4.69	14.72	11.18	^a	Doryx	YN
10176N NP	doxycycline 100 mg tablet, 21	1	..	..	10.03	11.18	^a	Doxycycline AN	EA
1800R NP	doxycycline 100 mg tablet, 21	1	..	..	10.03	11.18	^a	GenRx Doxycycline	GX
2714W NP	doxycycline 100 mg tablet, 7	3	..	..	*10.03	11.18	^a	Doxsig	QA
							^a	Doxy-100	GN
							^a	Doxycycline AN	EA
							^a	Doxylin 100	AF
9108J NP	doxycycline 100 mg tablet, 7	3	..	..	*10.03	11.18	^a	Chem mart Doxycycline	CH
							^a	Doxycycline Sandoz	HX
							^a	Terry White Chemists Doxycycline	TW

DOXYCYCLINE

Restricted benefit

Pelvic inflammatory disease

Note

Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hydrochloride), doxycycline tablet 100 mg (as monohydrate) and doxycycline capsule: modified release 100 mg (as hydrochloride) are equivalent for the purposes of substitution.

2703G NP	doxycycline 100 mg capsule: modified release, 7 capsules	4	..	^B 3.36	*14.48	12.27	^a	Mayne Pharma Doxycycline	YT
				^B 8.00	*19.12	12.27	^a	Doryx	YN
2702F NP	doxycycline 100 mg tablet, 7	4	..	..	*11.12	12.27	^a	Doxsig	QA
							^a	Doxy-100	GN
							^a	Doxylin 100	AF
9107H NP	doxycycline 100 mg tablet, 7	4	..	..	*11.12	12.27	^a	Chem mart Doxycycline	CH
							^a	Doxycycline Sandoz	HX
							^a	GenRx Doxycycline	GX
							^a	Terry White Chemists Doxycycline	TW

DOXYCYCLINE

Note

Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hydrochloride), doxycycline tablet 100 mg (as monohydrate) and doxycycline capsule: modified release 100 mg (as hydrochloride) are equivalent for the purposes of substitution.

2708M NP	doxycycline 100 mg capsule: modified release, 7 capsules	1	1	^B 0.84	8.69	9.00	^a	Mayne Pharma Doxycycline	YT
				^B 2.00	9.85	9.00	^a	Doryx	YN
3322W DP	doxycycline 100 mg capsule: modified release, 7 capsules	1	..	^B 0.84	8.69	9.00	^a	Mayne Pharma Doxycycline	YT
				^B 2.00	9.85	9.00	^a	Doryx	YN
2709N NP	doxycycline 100 mg tablet, 7	1	1	..	7.85	9.00	^a	Doxsig	QA
							^a	Doxy-100	GN

ANTIINFECTIVES FOR SYSTEMIC USE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
3321T <i>DP</i>	doxycycline 100 mg tablet, 7	1	..	..	7.85	9.00	^a Doxycycline AN	EA
							^a Doxylin 100	AF
							^a Doxsig	QA
5082L <i>DP</i>	doxycycline 100 mg tablet, 7	1	..	..	7.85	9.00	^a Doxy-100	GN
							^a Doxycycline AN	EA
							^a Doxylin 100	AF
9105F <i>NP</i>	doxycycline 100 mg tablet, 7	1	1	..	7.85	9.00	^a Chem mart Doxycycline	CH
							^a Doxycycline Sandoz	HX
							^a GenRx Doxycycline	GX
							^a Terry White Chemists Doxycycline	TW
							^a Chem mart Doxycycline	CH
							^a Doxycycline Sandoz	HX
							^a GenRx Doxycycline	GX
							^a Terry White Chemists Doxycycline	TW
							^a Doxycycline Sandoz	HX

DOXYCYCLINE

Restricted benefit

Bronchiectasis

Population criteria:

Patient must be aged 8 years or older.

Restricted benefit

Chronic bronchitis

Population criteria:

Patient must be aged 8 years or older.

Restricted benefit

Severe acne

Note

Pharmaceutical benefits that have the forms doxycycline tablet 50 mg (as hydrochloride), doxycycline tablet 50 mg (as monohydrate) and doxycycline capsule: modified release 50 mg (as hydrochloride) are equivalent for the purposes of substitution.

2707L <i>NP</i>	doxycycline 50 mg capsule: modified release, 25 capsules	1	5	^B 1.40	10.10	9.85	^a Mayne Pharma Doxycycline	YT
				^B 3.37	12.07	9.85	^a Doryx	YN
2711Q <i>NP</i>	doxycycline 50 mg tablet, 25	1	5	..	8.70	9.85	^a Doxy-50	GN
							^a Doxycycline AN	EA
9106G <i>NP</i>	doxycycline 50 mg tablet, 25	1	5	..	8.70	9.85	^a Doxylin 50	AF
							^a Chem mart Doxycycline	CH
							^a Doxycycline Sandoz	HX
							^a Frakas	QA
							^a GenRx Doxycycline	GX
							^a Terry White Chemists Doxycycline	TW

MINOCYCLINE

Restricted benefit

Severe acne not responding to other tetracyclines

Caution

There are concerns about the incidence of benign intracranial hypertension associated with this drug.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

1616C <i>NP</i>	minocycline 50 mg tablet, 60	1	5	..	15.39	16.54	^a Akamin 50	AF
				^B 1.89	17.28	16.54	^a Minomycin-50	QA

BETA-LACTAM ANTIBACTERIALS, PENICILLINS

Penicillins with extended spectrum

ANTIINFECTIVES FOR SYSTEMIC USE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
AMOXYCILLIN								
<u>Restricted benefit</u>								
Acute exacerbations of chronic bronchitis								
8581P NP	amoxycillin 1 g tablet, 14	1	1	..	8.34	9.49	^a Amoxycillin Sandoz	BG
				^b 0.41	8.75	9.49	^a Maxamox	SZ
AMOXYCILLIN								
1888J NP	amoxycillin 100 mg/mL oral liquid: powder for, 20 mL	‡1	1	[§] 0.61	#14.23	15.12	Amoxil	AS
3310F DP	amoxycillin 100 mg/mL oral liquid: powder for, 20 mL	‡1	..	[§] 0.61	#14.23	15.12	Amoxil	AS
1886G NP	amoxycillin 125 mg/5 mL oral liquid: powder for, 100 mL	‡1	1	..	#10.07	11.57	^a Alphamox 125	AF
							^a Amoxycillin Sandoz	SZ
							^a APO-Amoxycillin	TX
							^a Bgramin	GN
							^a Chem mart Amoxycillin	CH
							^a GenRx Amoxycillin	GX
							^a Ranmoxy	RA
							^a Terry White Chemists Amoxycillin	TW
				^b 2.89	#12.96	11.57	^a Amoxil	AS
3302T DP	amoxycillin 125 mg/5 mL oral liquid: powder for, 100 mL	‡1	..	..	#10.07	11.57	^a Alphamox 125	AF
							^a Amoxycillin Sandoz	SZ
							^a APO-Amoxycillin	TX
							^a Bgramin	GN
							^a Chem mart Amoxycillin	CH
							^a GenRx Amoxycillin	GX
							^a Ranmoxy	RA
							^a Terry White Chemists Amoxycillin	TW
				^b 2.89	#12.96	11.57	^a Amoxil	AS
1884E NP, MW	amoxycillin 250 mg capsule, 20	1	1	..	7.53	8.68	^a Alphamox 250	AF
							^a Amoxycillin AN	EA
							^a Amoxycillin-GA	GN
							^a Amoxycillin Ranbaxy	RA
							^a Amoxycillin Sandoz	SZ
							^a APO-Amoxycillin	TX
							^a Chem mart Amoxycillin	CH
							^a Cilamox	QA
							^a Terry White Chemists Amoxycillin	TW
				^b 2.89	10.42	8.68	^a Yomax 250	DO
				..	7.53	8.68	^a Amoxil	AS
3301R DP	amoxycillin 250 mg capsule, 20	1	..	..	7.53	8.68	^a Alphamox 250	AF
							^a Amoxycillin AN	EA
							^a Amoxycillin-GA	GN
							^a Amoxycillin Ranbaxy	RA
							^a Amoxycillin Sandoz	SZ
							^a APO-Amoxycillin	TX
							^a Chem mart Amoxycillin	CH
							^a Cilamox	QA
							^a Terry White Chemists Amoxycillin	TW
				^b 2.89	10.42	8.68	^a Yomax 250	DO
				..	#10.38	11.88	^a Amoxil	AS
1887H NP	amoxycillin 250 mg/5 mL oral liquid: powder for, 100 mL	‡1	1	..	#10.38	11.88	^a Alphamox 250	AF
							^a Amoxycillin Sandoz	SZ
							^a APO-Amoxycillin	TX

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$		Brand Name and Manufacturer	
3393N DP	amoxycillin 250 mg/5 mL oral liquid: powder for, 100 mL	‡1	..	B2.97 ..	#13.35 #10.38	11.88 11.88	a	Bgramin	GN
							a	Chem mart Amoxycillin	CH
							a	Cilamox	QA
							a	GenRx Amoxycillin	GX
							a	Ranmoxy	RA
							a	Terry White Chemists Amoxycillin	TW
							a	Amoxil Forte	AS
							a	Alphamox 250	AF
							a	Amoxycillin Sandoz	SZ
							a	APO-Amoxycillin	TX
							a	Bgramin	GN
							a	Chem mart Amoxycillin	CH
							a	Cilamox	QA
							a	GenRx Amoxycillin	GX
1889K NP,MW	amoxycillin 500 mg capsule, 20	1	1	B2.97 ..	#13.35 8.29	11.88 9.44	a	Terry White Chemists Amoxycillin	TW
							a	Amoxil Forte	AS
							a	Alphamox 500	AF
							a	Amoxycillin AN	EA
							a	Amoxycillin-GA	GN
							a	Amoxycillin	GQ
							a	generichealth 500	
							a	Amoxycillin Ranbaxy	RA
							a	Amoxycillin Sandoz	SZ
							a	APO-Amoxycillin	TX
							a	Chem mart Amoxycillin	CH
							a	Cilamox	QA
							a	Terry White Chemists Amoxycillin	TW
							3300Q DP	amoxycillin 500 mg capsule, 20	1
a	Amoxil	AS							
a	Alphamox 500	AF							
a	Amoxycillin AN	EA							
a	Amoxycillin-GA	GN							
a	Amoxycillin	GQ							
a	generichealth 500								
a	Amoxycillin Ranbaxy	RA							
a	Amoxycillin Sandoz	SZ							
a	APO-Amoxycillin	TX							
a	Chem mart Amoxycillin	CH							
a	Cilamox	QA							
a	Terry White Chemists Amoxycillin	TW							
5225B DP 8705E NP	amoxycillin 500 mg/5 mL oral liquid: powder for, 100 mL amoxycillin 500 mg/5 mL oral liquid: powder for, 100 mL	‡1 ‡1	.. 1	B3.06 ..	11.35 #11.47	9.44 12.97			
							a	Amoxil	AS
								Maxamox	SZ
							a	Amoxycillin AN	EA
							a	Amoxycillin-GA	GN
							a	Amoxycillin	GQ
							a	generichealth 500	
							a	Amoxycillin Ranbaxy	RA
							a	Amoxycillin Sandoz	SZ
							a	APO-Amoxycillin	TX
							a	Chem mart Amoxycillin	CH
							a	Cilamox	QA
							a	Terry White Chemists Amoxycillin	TW
							9714G NP	amoxycillin 100 mg/mL oral liquid: powder for, 20 mL	‡1
a	Austrapen	AL							
2977Q NP	ampicillin 1 g injection, 5 x 1 g vials	1	1	..	13.22	14.37	a	Ampicyn	AF
							a	Austrapen	AL

ANTIINFECTIVES FOR SYSTEMIC USE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
3314K DP	ampicillin 1 g injection, 5 x 1 g vials	1	..	..	13.22	14.37	^a Ibimicyc ^a Ampicyc	GN AF
2390T NP	ampicillin 500 mg injection, 5 x 500 mg vials	1	1	..	10.69	11.84	^a Austrapen ^a Ibimicyc ^a Austrapen	AL GN AL
3313J DP	ampicillin 500 mg injection, 5 x 500 mg vials	1	..	..	10.69	11.84	^a Ibimicyc ^a Austrapen ^a Ibimicyc	GN AL GN
Beta-lactamase sensitive penicillins								
BENZATHINE BENZYL PENICILLIN								
2267H NP	BENZATHINE BENZYL PENICILLIN Injection 900 mg in 2.3 mL single use pre-filled syringe, 10	1	..	..	318.90	37.70	Bicillin L-A	PF
5027N DP	BENZATHINE BENZYL PENICILLIN Injection 900 mg in 2.3 mL single use pre-filled syringe, 10	1	..	..	318.90	37.70	Bicillin L-A	PF
BENZYL PENICILLIN								
2647H NP	benzylpenicillin 3 g injection, 1 x 3 g vial	10	..	..	*89.86	37.70	BenPen	CS
3399X DP	benzylpenicillin 3 g injection, 1 x 3 g vial	10	..	..	*89.86	37.70	BenPen	CS
1775K NP, MW	benzylpenicillin 600 mg injection, 1 x 600 mg vial	10	1	..	*55.06	37.70	BenPen	CS
3398W DP	benzylpenicillin 600 mg injection, 1 x 600 mg vial	10	..	..	*55.06	37.70	BenPen	CS
PHENOXYMETHYL PENICILLIN								
5024K DP	phenoxymethylpenicillin 125 mg/5 mL oral liquid: powder for, 100 mL	2	..	..	*#17.15	18.65	Phenoxymethylpenicilli n-AFT	AE
8976K NP	phenoxymethylpenicillin 125 mg/5 mL oral liquid: powder for, 100 mL	2	1	..	*#17.15	18.65	Phenoxymethylpenicilli n-AFT	AE
5012T DP	phenoxymethylpenicillin 150 mg/5 mL oral liquid, 100 mL	2	..	..	*21.94	23.09	^a Cilicaine V	FM
9143F NP	phenoxymethylpenicillin 150 mg/5 mL oral liquid, 100 mL	2	1	^B 1.90	*23.84 *21.94	23.09 23.09	^a Abbecillin-V ^a Cilicaine V	QA FM
1789E NP	phenoxymethylpenicillin 250 mg capsule, 50	1	..	..	11.50	12.65	^a Abbecillin-V LPV ^a Cilicaine VK ^a Cilopen VK	QA IA FM GN
3363B DP	phenoxymethylpenicillin 250 mg capsule, 50	1	..	..	11.50	12.65	LPV ^a Cilicaine VK ^a Cilopen VK	IA FM GN
1787C NP	phenoxymethylpenicillin 250 mg tablet, 25	2	..	..	*11.66	12.81	Abbecillin-VK Filmstab	QA
3360W DP	phenoxymethylpenicillin 250 mg tablet, 25	2	..	..	*11.66	12.81	Abbecillin-VK Filmstab	QA
5029Q DP	phenoxymethylpenicillin 250 mg/5 mL oral liquid: powder for, 100 mL	2	..	..	*#19.71	21.21	Phenoxymethylpenicilli n-AFT	AE
8977L NP	phenoxymethylpenicillin 250 mg/5 mL oral liquid: powder for, 100 mL	2	1	..	*#19.71	21.21	Phenoxymethylpenicilli n-AFT	AE
2965C NP	phenoxymethylpenicillin 500 mg capsule, 50	1	..	..	13.81	14.96	LPV ^a Cilicaine VK ^a Cilopen VK	IA FM GN
3364C DP	phenoxymethylpenicillin 500 mg capsule, 50	1	..	..	13.81	14.96	^a Cilicaine VK ^a Cilopen VK	FM GN
3028J NP	phenoxymethylpenicillin 500 mg tablet, 25	2	..	..	*14.00	15.15	Abbecillin-VK Filmstab	QA

ANTIINFECTIVES FOR SYSTEMIC USE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
3361X DP	phenoxymethylpenicillin 500 mg tablet, 25	2	..	..	*14.00	15.15	Abbocillin-VK Filmtab	QA
PHENOXYMETHYLPENICILLIN								
<u>Restricted benefit</u>								
Prophylaxis of recurrent streptococcal infections (including rheumatic fever)								
1705R NP	phenoxymethylpenicillin 250 mg capsule, 50	1	5	..	11.50	12.65	^a Cilicaine VK	FM
							^a Cilopen VK LPV	GN IA
1703P NP	phenoxymethylpenicillin 250 mg tablet, 25	2	5	..	*11.66	12.81	Abbocillin-VK Filmtab	QA
PROCAINE PENICILLIN								
1794K NP	procaine penicillin 1.5 g/3.4 mL injection, 5 x 3.4 mL syringes	1	..	..	92.56	37.70	Cilicaine	QA
3371K DP	procaine penicillin 1.5 g/3.4 mL injection, 5 x 3.4 mL syringes	1	..	..	92.56	37.70	Cilicaine	QA
<i>Beta-lactamase resistant penicillins</i>								
DICLOXACILLIN								
<u>Restricted benefit</u>								
Serious staphylococcal infections								
5096F DP	dicloxacillin 250 mg capsule, 24	1	..	..	13.10	14.25	Distaph 250	AF
8121K NP,MW	dicloxacillin 250 mg capsule, 24	1	..	..	13.10	14.25	Distaph 250	AF
5097G DP	dicloxacillin 500 mg capsule, 24	1	..	..	17.85	19.00	Distaph 500	AF
8122L NP,MW	dicloxacillin 500 mg capsule, 24	1	..	..	17.85	19.00	Distaph 500	AF
FLUCLOXACILLIN								
<u>Caution</u>								
Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.								
1525G NP	flucloxacillin 1 g injection, 5 x 1 g vials	1	1	..	11.91	13.06	^a Flubiclox	GN
							^a Flucil	AS
							^a Hospira Pty Limited	HH
5095E DP	flucloxacillin 1 g injection, 5 x 1 g vials	1	..	..	11.91	13.06	^a Flubiclox	GN
							^a Flucil	AS
							^a Hospira Pty Limited	HH
1524F NP	flucloxacillin 500 mg injection, 5 x 500 mg vials	1	..	..	10.05	11.20	^a Flubiclox	GN
							^a Flucil	AS
5094D DP	flucloxacillin 500 mg injection, 5 x 500 mg vials	1	..	..	10.05	11.20	^a Flubiclox	GN
							^a Flucil	AS
FLUCLOXACILLIN								
<u>Restricted benefit</u>								
Serious staphylococcal infections								
<u>Caution</u>								
Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.								
5257Q DP	flucloxacillin 125 mg/5 mL oral liquid: powder for, 100 mL	#1	..	..	#16.44	17.94	Flucil	LN
9149M NP	flucloxacillin 125 mg/5 mL oral liquid: powder for, 100 mL	#1	..	..	#16.44	17.94	Flucil	LN
1526H NP,MW	flucloxacillin 250 mg capsule, 24	1	..	..	11.53	12.68	^a Flopen	AS
							^a Staphylex 250	AF
5090X DP	flucloxacillin 250 mg capsule, 24	1	..	..	11.53	12.68	^a Flopen	AS
							^a Staphylex 250	AF

ANTIINFECTIVES FOR SYSTEMIC USE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
5258R DP	flucloxacillin 250 mg/5 mL oral liquid: powder for, 100 mL	‡1	..	..	#19.97	21.47	Flucil	LN
9150N NP	flucloxacillin 250 mg/5 mL oral liquid: powder for, 100 mL	‡1	..	..	#19.97	21.47	Flucil	LN
1527J NP,MW	flucloxacillin 500 mg capsule, 24	1	..	..	16.75	17.90	^a Flopen	AS
5091Y DP	flucloxacillin 500 mg capsule, 24	1	..	..	16.75	17.90	^a Staphylex 500 ^a Flopen	AF AS
							^a Staphylex 500	AF

Combinations of penicillins, incl. beta-lactamase inhibitors

AMOXYCILLIN + CLAVULANIC ACID

Restricted benefit

Infections where resistance to amoxycillin is suspected

Restricted benefit

Infections where resistance to amoxycillin is proven

Caution

Hepatotoxicity has been reported with this drug.

1892N NP	amoxycillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL oral liquid: powder for, 75 mL	‡1	1	..	#10.76	12.26	^a APO-Amoxycillin and Clavulanic Acid 125/31.25	TX
							^a Clamoxyl	AL
							^a Curam	SZ
							^a GA-Amclav 125/31.25	GN
				^B 2.89	#13.65	12.26	^a Augmentin	AS
5009P DP	amoxycillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL oral liquid: powder for, 75 mL	‡1	..	..	#10.76	12.26	^a APO-Amoxycillin and Clavulanic Acid 125/31.25	TX
							^a Clamoxyl	AL
							^a Curam	SZ
							^a GA-Amclav 125/31.25	GN
				^B 2.89	#13.65	12.26	^a Augmentin	AS
5011R DP	amoxycillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL oral liquid: powder for, 60 mL	‡1	..	..	#11.36	12.86	^a APO-Amoxycillin and Clavulanic Acid 400/57	TX
							^a Clamoxyl Duo 400	AL
							^a Curam Duo	SZ
							^a GA-Amclav Forte 400/57	GN
				^B 4.06	#15.42	12.86	^a Augmentin Duo 400	AS
8319W NP	amoxycillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL oral liquid: powder for, 60 mL	‡1	1	..	#11.36	12.86	^a APO-Amoxycillin and Clavulanic Acid 400/57	TX
							^a Clamoxyl Duo 400	AL
							^a Curam Duo	SZ
							^a GA-Amclav Forte 400/57	GN
				^B 4.06	#15.42	12.86	^a Augmentin Duo 400	AS
1891M NP,MW	amoxycillin 500 mg + clavulanic acid 125 mg tablet, 10	1	1	..	9.00	10.15	^a Amoxyclav AN 500/125	EA
							^a APO-Amoxycillin/Clavulanic Acid 500/125	TX
							^a Clamoxyl Duo	AL
							^a Curam Duo 500/125	SZ
							^a GA-Amclav 500/125	GN
							^a Moxiclav Duo 500/125	QA
							^a Pharmacor AmoxyClav 500/125	CR
				^B 4.00	13.00	10.15	^a Augmentin Duo	AS
5008N DP	amoxycillin 500 mg + clavulanic acid 125 mg tablet, 10	1	..	..	9.00	10.15	^a Amoxyclav AN 500/125	EA
							^a APO-Amoxycillin/Clavulanic Acid 500/125	TX

ANTIINFECTIVES FOR SYSTEMIC USE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
5006L DP	amoxycillin 875 mg + clavulanic acid 125 mg tablet, 10	1	..	..	13.00	10.15	a Clamoxyl Duo	AL
							a Curam Duo 500/125	SZ
							a GA-Amclav 500/125	GN
							a Moxiclav Duo 500/125	QA
							a Pharmacor AmoxyClav 500/125	CR
							a Augmentin Duo	AS
							a Amoxyclav AN 875/125	EA
							a AmoxyClav GH 875/125	GQ
							a AmoxyClav RBX 875/125	RA
							a APO-Amoxycillin and Clavulanic Acid	TX
							a Chem mart Amoxycillin and Clavulanic Acid	CH
							a Clamoxyl Duo forte	AL
							a Clavam 875 mg/125 mg	NJ
							a Curam Duo Forte 875/125	SZ
							a GA-Amclav Forte 875/125	GN
							a Moxiclav Duo Forte 875/125	QA
							a Pharmacor AmoxyClav 875/125	CR
							a Terry White Chemists Amoxycillin and Clavulanic Acid	TW
							a Augmentin Duo forte	AS
8254K NP	amoxycillin 875 mg + clavulanic acid 125 mg tablet, 10	1	1	..	15.07	11.10	a Amoxyclav AN 875/125	EA
							a AmoxyClav GH 875/125	GQ
							a AmoxyClav RBX 875/125	RA
							a APO-Amoxycillin and Clavulanic Acid	TX
							a Chem mart Amoxycillin and Clavulanic Acid	CH
							a Clamoxyl Duo forte	AL
							a Clavam 875 mg/125 mg	NJ
							a Curam Duo Forte 875/125	SZ
							a GA-Amclav Forte 875/125	GN
							a Moxiclav Duo Forte 875/125	QA
							a Pharmacor AmoxyClav 875/125	CR
							a Terry White Chemists Amoxycillin and Clavulanic Acid	TW
							a Augmentin Duo forte	AS
							a AmoxyClav GH 875/125	GQ
							a AmoxyClav RBX 875/125	RA
							a APO-Amoxycillin and Clavulanic Acid	TX
							a Chem mart Amoxycillin and Clavulanic Acid	CH
							a Clamoxyl Duo forte	AL
							a Clavam 875 mg/125 mg	NJ
							a Curam Duo Forte 875/125	SZ
							a GA-Amclav Forte 875/125	GN
							a Moxiclav Duo Forte 875/125	QA
							a Pharmacor AmoxyClav 875/125	CR
							a Terry White Chemists Amoxycillin and Clavulanic Acid	TW
							a Augmentin Duo forte	AS

TICARCILLIN + CLAVULANIC ACID

Restricted benefit

Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

Restricted benefit

Septicaemia, suspected

Restricted benefit

Septicaemia, proven

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

10113G	ticarcillin 3 g + clavulanic acid 100 mg	10	..	..	*163.76	37.70	Timentin	AS

ANTIINFECTIVES FOR SYSTEMIC USE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
NP	injection, 1 x 3.1 g vial							
TICARCILLIN + CLAVULANIC ACID								
<u>Restricted benefit</u>								
Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent								
10125X DP	ticarillin 3 g + clavulanic acid 100 mg injection, 1 x 3.1 g vial	10	..	..	*163.76	37.70	Timentin	AS
OTHER BETA-LACTAM ANTIBACTERIALS								
<i>First-generation cephalosporins</i>								
CEPHALEXIN								
3094W NP	cephalexin 125 mg/5 mL oral liquid: powder for, 100 mL	\$1	1	..	#10.74	12.24	a APO-Cephalexin	TX
							a Cefalexin Sandoz	SZ
							a Chem mart Cephalexin	CH
							a Cillex	GN
							a Ialex	LN
							a Ibilex 125	AF
							a Terry White Chemists Cephalexin	TW
				^B 4.77	#15.51	12.24	a Keflex	AS
3319Q DP	cephalexin 125 mg/5 mL oral liquid: powder for, 100 mL	\$1	..	..	#10.74	12.24	a APO-Cephalexin	TX
							a Cefalexin Sandoz	SZ
							a Chem mart Cephalexin	CH
							a Cillex	GN
							a Ialex	LN
							a Ibilex 125	AF
							a Terry White Chemists Cephalexin	TW
				^B 4.77	#15.51	12.24	a Keflex	AS
3058Y NP,MW	cephalexin 250 mg capsule, 20	1	1	..	7.89	9.04	a APO-Cephalexin	TX
							a Cefalexin Sandoz	SZ
							a Cephalax 250	CR
							a Cephalaxin AN	EA
							a Cephalaxin generichealth	GQ
							a Chem mart Cephalexin	CH
							a Cillex	GN
							a GenRx Cephalexin	GX
							a Ialex	LN
							a Ibilex 250	AF
							a Rancef	RA
							a Terry White Chemists Cephalexin	TW
				^B 4.32	12.21	9.04	a Keflex	AS
3317N DP	cephalexin 250 mg capsule, 20	1	..	..	7.89	9.04	a APO-Cephalexin	TX
							a Cefalexin Sandoz	SZ
							a Cephalax 250	CR
							a Cephalaxin AN	EA
							a Cephalaxin generichealth	GQ
							a Chem mart Cephalexin	CH
							a Cillex	GN
							a GenRx Cephalexin	GX
							a Ialex	LN
							a Ibilex 250	AF
							a Rancef	RA
							a Terry White Chemists Cephalexin	TW
				^B 4.32	12.21	9.04	a Keflex	AS
3095X NP	cephalexin 250 mg/5 mL oral liquid: powder for, 100 mL	\$1	1	..	#11.39	12.89	a APO-Cephalexin	TX

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer						
3320R DP	cephalexin 250 mg/5 mL oral liquid: powder for, 100 mL	‡1	..	B6.23 ..	#17.62 #11.39	12.89 12.89	a Cefalexin Sandoz SZ						
							a Chem mart Cephalixin CH						
							a Cilex GN						
							a Ialex LN						
							a Ibilex 250 AF						
							a Terry White Chemists Cephalixin TW						
							a Keflex AS						
							a APO-Cephalixin TX						
							a Cefalexin Sandoz SZ						
							a Chem mart Cephalixin CH						
3119E NP,MW	cephalexin 500 mg capsule, 20	1	1	B6.23 ..	#17.62 8.78	12.89 9.93	a Cilex GN						
							a Ialex LN						
							a Ibilex 250 AF						
							a Terry White Chemists Cephalixin TW						
							a Keflex AS						
							a APO-Cephalixin TX						
							a Cefalexin Sandoz SZ						
							a Cephalix 500 NJ						
							a Cephalixin AN EA						
							a Cephalixin generichealth GQ						
3318P DP	cephalexin 500 mg capsule, 20	1	..	B6.31 ..	15.09 8.78	9.93 9.93	a Chem mart Cephalixin CH						
							a Cilex GN						
							a GenRx Cephalixin GX						
							a Ialex LN						
							a Ibilex 500 AF						
							a Pharmacor Cephalixin 500 CR						
							a Rancef RA						
							a Terry White Chemists Cephalixin TW						
							a Keflex AS						
							a APO-Cephalixin TX						
							a Cefalexin Sandoz SZ						
							a Cephalix 500 NJ						
							a Cephalixin AN EA						
							a Cephalixin generichealth GQ						
							a Chem mart Cephalixin CH						
							a Cilex GN						
							a GenRx Cephalixin GX						
							a Ialex LN						
							a Ibilex 500 AF						
							a Pharmacor Cephalixin 500 CR						
				B6.31	15.09	9.93	a Rancef RA						
							a Terry White Chemists Cephalixin TW						
							a Keflex AS						
CEPHALEXIN													
Authority required (STREAMLINED)													
4243													
Prophylaxis of urinary tract infection													
2655R	cephalexin 250 mg capsule, 20	2	2	..	*9.02	10.17	a APO-Cephalixin TX						
							a Cefalexin Sandoz SZ						
							a Cephalix 250 CR						
							a Cephalixin AN EA						
							a Cephalixin GO						

ANTIINFECTIVES FOR SYSTEMIC USE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							generichealth	
							a Chem mart Cephalixin	CH
							a Cilex	GN
							a GenRx Cephalixin	GX
							a Ialex	LN
							a Ibilex 250	AF
							a Rancef	RA
							a Terry White Chemists Cephalixin	TW
				^b 8.64	*17.66	10.17	a Keflex	AS
CEPHALOTHIN								
2964B	cephalothin 1 g injection, 10 x 1 g vials	1	1	..	19.32	20.47	Hospira Pty Limited	HH
NP								
3376Q	cephalothin 1 g injection, 10 x 1 g vials	1	..	..	19.32	20.47	Hospira Pty Limited	HH
DP								
CEPHAZOLIN								
<u>Restricted benefit</u>								
Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent								
<u>Restricted benefit</u>								
Septicaemia, suspected								
<u>Restricted benefit</u>								
Septicaemia, proven								
<u>Note</u>								
For item codes 1257E and 1797N, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.								
<u>Note</u>								
Shared Care Model:								
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
1257E	cephazolin 1 g injection, 10 x 1 g vials	1	..	..	14.20	15.35	a Cefazolin Sandoz	SZ
NP								
1797N	cephazolin 1 g injection, 5 x 1 g vials	2	..	..	*14.22	15.37	a Cefazolin-AFT	AE
NP							a Hospira Cefazolin Sodium	HH
CEPHAZOLIN								
<u>Restricted benefit</u>								
Cellulitis								
<u>Note</u>								
For item codes 5478H and 1799Q, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.								
5478H	cephazolin 1 g injection, 10 x 1 g vials	1	..	..	14.20	15.35	a Cefazolin Sandoz	SZ
NP								
1799Q	cephazolin 1 g injection, 5 x 1 g vials	2	..	..	*14.22	15.37	a Cefazolin-AFT	AE
NP							a Hospira Cefazolin Sodium	HH
CEPHAZOLIN								
<u>Restricted benefit</u>								
Cellulitis								
5479J	cephazolin 2 g injection, 1 x 2 g vial	10	..	..	*23.76	24.91	a Cefazolin Sandoz	SZ
NP								
5477G	cephazolin 500 mg injection, 5 x 500 mg vials	2	..	..	*12.38	13.53	a Cephazolin Alphapharm	AF
NP							Cefazolin-AFT	AE

CEPHAZOLIN

Restricted benefit

Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

Restricted benefit

ANTIINFECTIVES FOR SYSTEMIC USE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Septicaemia, suspected							
	<u>Restricted benefit</u>							
	Septicaemia, proven							
	<u>Note</u>							
	Shared Care Model:							
	For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
9326W NP	cephazolin 2 g injection, 1 x 2 g vial	10	..	..	*23.76	24.91	^a Cefazolin Sandoz	SZ
1256D NP	cephazolin 500 mg injection, 5 x 500 mg vials	2	..	..	*12.38	13.53	^a Cephazolin Alphapharm Cefazolin-AFT	AF AE
Second-generation cephalosporins								
CEFACLOR								
<u>Caution</u>								
Serum sickness-like reactions have been reported with this drug, especially in children.								
2460L	cefaclor 125 mg/5 mL oral liquid: powder for, 100 mL	‡1	1	..	#12.07	13.57	^a Aclor 125	QA
							^a APO-Cefaclor	TX
							^a GenRx Cefaclor	GX
							^a Keflor	AF
				^B 5.86	#17.93	13.57	^a Ceclor	AS
5046N DP	cefaclor 125 mg/5 mL oral liquid: powder for, 100 mL	‡1	..	..	#12.07	13.57	^a Aclor 125	QA
							^a APO-Cefaclor	TX
							^a GenRx Cefaclor	GX
							^a Keflor	AF
				^B 5.86	#17.93	13.57	^a Ceclor	AS
2461M	cefaclor 250 mg/5 mL oral liquid: powder for, 75 mL	‡1	1	..	#12.28	13.78	^a Aclor 250	QA
							^a APO-Cefaclor	TX
							^a GenRx Cefaclor	GX
							^a Keflor	AF
				^B 6.10	#18.38	13.78	^a Ceclor	AS
5047P DP	cefaclor 250 mg/5 mL oral liquid: powder for, 75 mL	‡1	..	..	#12.28	13.78	^a Aclor 250	QA
							^a APO-Cefaclor	TX
							^a GenRx Cefaclor	GX
							^a Keflor	AF
				^B 6.10	#18.38	13.78	^a Ceclor	AS
1169M	cefaclor 375 mg tablet: modified release, 10	1	1	..	10.59	11.74	^a APO-Cefaclor CD	TX
							^a Cefaclor-GA	GN
							^a Cefaclor GH	GQ
							^a Chem mart Cefaclor CD	CH
							^a GenRx Cefaclor CD	GX
							^a Karlor CD	LN
							^a Keflor CD	AF
							^a Ozcef	RA
							^a Terry White Chemists Cefaclor CD	TW
				^B 7.20	17.79	11.74	^a Ceclor CD	AS
5045M DP	cefaclor 375 mg tablet: modified release, 10	1	..	..	10.59	11.74	^a APO-Cefaclor CD	TX
							^a Cefaclor-GA	GN
							^a Cefaclor GH	GQ
							^a Chem mart Cefaclor CD	CH
							^a GenRx Cefaclor CD	GX
							^a Karlor CD	LN
							^a Keflor CD	AF
							^a Ozcef	RA
							^a Terry White Chemists	TW

ANTIINFECTIVES FOR SYSTEMIC USE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
				^a 7.20	17.79	11.74	^a Cefaclor CD Ceclor CD	AS
CEFUROXIME								
2002J DP	CEFUROXIME AXETIL Powder for oral suspension 125 mg (base) per 5 mL, 70 mL, 1	‡1	..	..	#19.80	21.30	Zinnat	AS
5499K	CEFUROXIME AXETIL Powder for oral suspension 125 mg (base) per 5 mL, 70 mL, 1	‡1	1	..	#19.80	21.30	Zinnat	AS
5052X DP	cefuroxime 250 mg tablet, 14	1	..	..	18.96	20.11	Zinnat	AS
8292K	cefuroxime 250 mg tablet, 14	1	1	..	18.96	20.11	Zinnat	AS

Third-generation cephalosporins

CEFOTAXIME

Restricted benefit

Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

Restricted benefit

Septicaemia, suspected

Restricted benefit

Septicaemia, proven

Note

For item codes 1085D and 1758M, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1758M NP	CEFOTAXIME Powder for injection 1 g, 10	1	..	..	21.47	22.62	^a Hospira Pty Limited	HH
1085D NP	cefotaxime 1 g injection, 1 x 1 g vial	10	..	..	*21.46	22.61	^a Cefotaxime Sandoz	SZ

CEFOTAXIME

Restricted benefit

Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

Note

For item codes 5048Q and 1768C, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.

1768C DP	CEFOTAXIME Powder for injection 1 g, 10	1	..	..	21.47	22.62	^a Hospira Pty Limited	HH
5048Q DP	cefotaxime 1 g injection, 1 x 1 g vial	10	..	..	*21.46	22.61	^a Cefotaxime Sandoz	SZ

CEFOTAXIME

Restricted benefit

Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

Restricted benefit

Septicaemia, suspected

Restricted benefit

Septicaemia, proven

Note

For item codes 1086E and 1759N, pharmaceutical benefits that have the form powder for injection 2 g are equivalent for the purposes of substitution.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1759N NP	CEFOTAXIME Powder for injection 2 g, 10	1	..	..	33.96	35.11	^a Hospira Pty Limited	HH
1086E	cefotaxime 2 g injection, 1 x 2 g vial	10	..	..	*34.06	35.21	^a Cefotaxime Sandoz	SZ

ANTIINFECTIVES FOR SYSTEMIC USE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
NP								
CEFOTAXIME								
<u>Restricted benefit</u>								
Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent								
<u>Note</u>								
For item codes 5049R and 1769D, pharmaceutical benefits that have the form powder for injection 2 g are equivalent for the purposes of substitution.								
1769D DP	CEFOTAXIME Powder for injection 2 g, 10	1	..	..	33.96	35.11	^a Hospira Pty Limited	HH
5049R DP	cefotaxime 2 g injection, 1 x 2 g vial	10	..	..	*34.06	35.21	^a Cefotaxime Sandoz	SZ
CEFTRIAXONE								
<u>Restricted benefit</u>								
Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent								
<u>Restricted benefit</u>								
Septicaemia, suspected								
<u>Restricted benefit</u>								
Septicaemia, proven								
<u>Note</u>								
For item codes 1784X and 1788D, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.								
<u>Note</u>								
Shared Care Model:								
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
1788D NP	CEFTRIAXONE Powder for injection 1 g, 5	1	..	..	13.68	14.83	^a Ceftriaxone Alphapharm	AF
							^a Max Pharma	GQ
1784X NP	ceftriaxone 1 g injection, 1 x 1 g vial	5	..	..	*13.66	14.81	^a Ceftriaxone	AE
							^a Ceftriaxone-AFT	AE
							^a Ceftriaxone ICP	PP
							^a Ceftriaxone Sandoz	SZ
							^a Hospira Ceftriaxone	HH
CEFTRIAXONE								
<u>Restricted benefit</u>								
Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent								
<u>Restricted benefit</u>								
Septicaemia, suspected								
<u>Restricted benefit</u>								
Septicaemia, proven								
<u>Note</u>								
Shared Care Model:								
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
1785Y NP	ceftriaxone 2 g injection, 1 x 2 g vial	5	..	..	*19.56	20.71	^a Ceftriaxone-AFT	AE
							^a Ceftriaxone Alphapharm	AF
							^a Ceftriaxone Sandoz	SZ
							^a Hospira Ceftriaxone	HH
1783W NP	ceftriaxone 500 mg injection, 1 x 500 mg vial	5	..	..	*11.11	12.26	^a Ceftriaxone-AFT	AE
							^a Ceftriaxone ICP	PP
CEFTRIAXONE								
<u>Restricted benefit</u>								
Gonorrhoea								
9058R NP	ceftriaxone 500 mg injection, 1 x 500 mg vial	1	..	..	7.63	8.78	^a Ceftriaxone-AFT	AE

ANTIINFECTIVES FOR SYSTEMIC USE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							^a Ceftriaxone ICP	PP
Fourth-generation cephalosporins								
CEFEPIME								
Authority required								
Treatment of febrile neutropenia								
Note								
Shared Care Model:								
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8315P NP	CEFEPIME Powder for injection 1 g (as hydrochloride), 1	10	..	..	*60.66	37.70	^a Cefepime-AFT	AE
							^a Cefepime Alphapharm	AF
							^a Cefepime Sandoz	SZ
							^a DBL Cefepime	HH
							^a Omegapharm Pty Ltd	OE
8316Q NP	CEFEPIME Powder for injection 2 g (as hydrochloride), 1	10	..	..	*109.36	37.70	^a Cefepime-AFT	AE
							^a Cefepime Alphapharm	AF
							^a Cefepime Sandoz	SZ
							^a DBL Cefepime	HH
							^a Omegapharm Pty Ltd	OE

SULFONAMIDES AND TRIMETHOPRIM

Trimethoprim and derivatives

TRIMETHOPRIM

Authority required (STREAMLINED)

4243

Prophylaxis of urinary tract infection

2666H	trimethoprim 300 mg tablet, 7	2	2	..	*10.68	11.83	^a Alprim	AF
				^B 3.78	*14.46	11.83	^a Triprim	QA
TRIMETHOPRIM								
2922T NP	trimethoprim 300 mg tablet, 7	1	1	..	8.72	9.87	^a Alprim	AF
				^B 1.89	10.61	9.87	^a Triprim	QA

Combinations of sulfonamides and trimethoprim, incl. derivatives

TRIMETHOPRIM + SULFAMETHOXAZOLE

Caution

There is an increased risk of severe adverse reactions with this combination in the elderly.

2951H NP	trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10	1	1	..	9.58	10.73	^a Bactrim DS	RO
				^B 3.90	13.48	10.73	^a Resprim Forte	AF
				..	9.58	10.73	^a Septrin Forte	QA
3390K DP	trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10	1	..	..	9.58	10.73	^a Bactrim DS	RO
				^B 3.90	13.48	10.73	^a Resprim Forte	AF
				..	9.27	10.42	^a Septrin Forte	QA
3103H NP	trimethoprim 40 mg/5 mL + sulfamethoxazole 200 mg/5 mL oral liquid, 100 mL	‡1	1	..	9.27	10.42	Bactrim	RO
				^B 4.25	13.52	10.42	Septin	QA
3391L DP	trimethoprim 40 mg/5 mL + sulfamethoxazole 200 mg/5 mL oral liquid, 100 mL	‡1	..	..	9.27	10.42	Bactrim	RO
				^B 4.25	13.52	10.42	Septin	QA

MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

Macrolides

AZITHROMYCIN

Restricted benefit

ANTIINFECTIVES FOR SYSTEMIC USE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Trachoma							
	Note							
	No applications for increased maximum quantities and/or repeats will be authorised.							
8201P NP	azithromycin 200 mg/5 mL oral liquid: powder for, 15 mL	‡1	..	..	#23.70	25.20	Zithromax	PF
8336R NP	azithromycin 500 mg tablet, 2	1	2	..	13.25	14.40	^a APO-Azithromycin	TX
							^a Azithromycin-GA	UA
							^a Azithromycin Sandoz	SZ
							^a Chem mart	CH
							Azithromycin	
							^a Terry White Chemists	TW
							Azithromycin	
							^a Zithromax	PF
							^a Zitrocin	GN
	AZITHROMYCIN							
	Restricted benefit							
	Uncomplicated urethritis due to Chlamydia trachomatis							
	Restricted benefit							
	Uncomplicated cervicitis due to Chlamydia trachomatis							
	Note							
	No applications for increased maximum quantities and/or repeats will be authorised.							
8200N NP	azithromycin 500 mg tablet, 2	1	..	..	13.25	14.40	^a APO-Azithromycin	TX
							^a Azithromycin-GA	UA
							^a Azithromycin Sandoz	SZ
							^a Chem mart	CH
							Azithromycin	
							^a Terry White Chemists	TW
							Azithromycin	
							^a Zithromax	PF
							^a Zitrocin	GN
	CLARITHROMYCIN							
8318T NP	clarithromycin 250 mg tablet, 14	1	1	..	10.22	11.37	^a APO-Clarithromycin	TX
							^a Chem mart	CH
							Clarithromycin	
							^a Clarac	GN
							^a Clarihexal	HX
							^a Clarithro 250	QA
							^a Clarithromycin AN	EA
							^a Clarithromycin Sandoz	SZ
							^a Kalixocin	AF
							^a Terry White Chemists	TW
							Clarithromycin	
				^b 3.50	13.72	11.37	^a Klacid	GO
	CLARITHROMYCIN							
	Restricted benefit							
	Bordetella pertussis							
	Restricted benefit							
	Atypical mycobacterial infections							
9192T NP	clarithromycin 250 mg/5 mL oral liquid: powder for, 50 mL	‡1	..	..	#27.92	29.42	Klacid	GO
	ERYTHROMYCIN							
1404X NP	erythromycin 250 mg capsule: enteric, 25	1	1	..	11.03	12.18	^a Mayne Pharma	YT
							Erythromycin	
				^b 2.91	13.94	12.18	^a Eryc	YN
3325B DP	erythromycin 250 mg capsule: enteric, 25	1	..	..	11.03	12.18	^a Mayne Pharma	YT
							Erythromycin	
				^b 2.91	13.94	12.18	^a Eryc	YN

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
ERYTHROMYCIN ETHYLSUCCINATE								
2424N NP	erythromycin (as ethylsuccinate) 200 mg/5 mL oral liquid: powder for, 100 mL	‡1	1	..	#14.91	16.41	^a E-Mycin 200	AF
				^B 2.71	#17.62	16.41	^a E.E.S. 200	LM
3334L DP	erythromycin (as ethylsuccinate) 200 mg/5 mL oral liquid: powder for, 100 mL	‡1	..	..	#14.91	16.41	^a E-Mycin 200	AF
				^B 2.71	#17.62	16.41	^a E.E.S. 200	LM
2750R NP	erythromycin (as ethylsuccinate) 400 mg tablet, 25	1	1	..	12.40	13.55	^a E-Mycin	AF
				^B 2.67	15.07	13.55	^a E.E.S. 400 Filmtab	LM
3336N DP	erythromycin (as ethylsuccinate) 400 mg tablet, 25	1	..	..	12.40	13.55	^a E-Mycin	AF
				^B 2.67	15.07	13.55	^a E.E.S. 400 Filmtab	LM
2428T NP	erythromycin (as ethylsuccinate) 400 mg/5 mL oral liquid: powder for, 100 mL	‡1	1	..	#16.42	17.92	^a E-Mycin 400	AF
				^B 2.73	#19.15	17.92	^a E.E.S. Granules	LM
3337P DP	erythromycin (as ethylsuccinate) 400 mg/5 mL oral liquid: powder for, 100 mL	‡1	..	..	#16.42	17.92	^a E-Mycin 400	AF
				^B 2.73	#19.15	17.92	^a E.E.S. Granules	LM
ERYTHROMYCIN LACTOBIONATE								
1397M NP	erythromycin (as lactobionate) 1 g injection, 1 x 1 g vial	5	..	..	*196.81	37.70	Erythrocin-I.V.	LM
5088T DP	erythromycin (as lactobionate) 1 g injection, 1 x 1 g vial	5	..	..	*196.81	37.70	Erythrocin-I.V.	LM
ROXITHROMYCIN								
1760P NP	roxithromycin 150 mg tablet, 10	1	1	..	8.96	10.11	^a APO-Roxithromycin	TX
							^a Biaxsig	AV
							^a Chem mart	CH
							^a Roxithromycin	
							^a Roxar 150	QA
							^a Roximycin	AF
							^a Roxithromycin AN	EA
							^a Roxithromycin-GA	GN
							^a Roxithromycin GH	GQ
							^a Roxithromycin Sandoz	SZ
							^a Roxithromycin SCP 150	CR
							^a Terry White Chemists	TW
							^a Roxithromycin	
				^B 2.12	11.08	10.11	^a Rulide	SW
5260W DP	roxithromycin 150 mg tablet, 10	1	..	..	8.96	10.11	^a APO-Roxithromycin	TX
							^a Biaxsig	AV
							^a Chem mart	CH
							^a Roxithromycin	
							^a Roxar 150	QA
							^a Roximycin	AF
							^a Roxithromycin AN	EA
							^a Roxithromycin-GA	GN
							^a Roxithromycin GH	GQ
							^a Roxithromycin Sandoz	SZ
							^a Roxithromycin SCP 150	CR
							^a Terry White Chemists	TW
							^a Roxithromycin	
				^B 2.12	11.08	10.11	^a Rulide	SW
5261X DP	roxithromycin 300 mg tablet, 5	1	..	..	8.96	10.11	^a APO-Roxithromycin	TX
							^a Biaxsig	AV
							^a Chem mart	CH
							^a Roxithromycin	

ANTIINFECTIVES FOR SYSTEMIC USE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
8016X NP	roxithromycin 300 mg tablet, 5	1	1	2.12 ..	11.08 8.96	10.11 10.11	a Roxar 300	QA
							a Roximycin	AF
							a Roxithromycin AN	EA
							a Roxithromycin-GA	GN
							a Roxithromycin GH	GQ
							a Roxithromycin Sandoz	SZ
							a Roxithromycin SCP 300	CR
							a Terry White Chemists Roxithromycin	TW
							a Rulide	SW
							a APO-Roxithromycin	TX
							a Biaxsig	AV
							a Chem mart Roxithromycin	CH
							a Roxar 300	QA
							a Roximycin	AF
							a Roxithromycin AN	EA
5259T DP	roxithromycin 50 mg tablet: dispersible, 10	1	..	2.12 ..	11.08 13.23	10.11 14.38	a Rulide	SW
							Rulide D	SW
8129W NP	roxithromycin 50 mg tablet: dispersible, 10	1	1	..	13.23	14.38	Rulide D	SW

Lincosamides

CLINDAMYCIN

Restricted benefit

Gram-positive coccal infections where these cannot be safely and effectively treated with a penicillin

3138E NP,MW	clindamycin 150 mg capsule, 24	1	..	..	17.96	19.11	a APO-Clindamycin	TX
							a Chem mart Clindamycin	CH
							a Cleocin	FZ
							a Clindamycin-Link	LM
							a Terry White Chemists Clindamycin	TW
5057E DP	clindamycin 150 mg capsule, 24	1	..	1.71 ..	19.67 17.96	19.11 19.11	a Dalacin C	PF
							a APO-Clindamycin	TX
							a Chem mart Clindamycin	CH
							a Cleocin	FZ
							a Clindamycin-Link	LM
				1.71	19.67	19.11	a Terry White Chemists Clindamycin	TW
							a Dalacin C	PF

LINCOMYCIN

2530E NP,MW	lincomycin 600 mg/2 mL injection, 5 x 2 mL vials	1	..	..	159.33	37.70	Lincocin	PF
5144R DP	lincomycin 600 mg/2 mL injection, 5 x 2 mL vials	1	..	..	159.33	37.70	Lincocin	PF

AMINOGLYCOSIDE ANTIBACTERIALS

Other aminoglycosides

GENTAMICIN

2824P NP	gentamicin 80 mg/2 mL injection, 10 x 2 mL ampoules	1	1	..	20.01	21.16	Pfizer Australia Pty Ltd	PF

TOBRAMYCIN

Authority required (STREAMLINED)

4456

ANTIINFECTIVES FOR SYSTEMIC USE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Proven Pseudomonas aeruginosa infection							
	Treatment Phase: Initial treatment							
	Clinical criteria:							
	Patient must have cystic fibrosis,							
	AND							
	Patient must have been assessed for bronchial hyperresponsiveness as per the TGA-approved Product Information, with a negative test result,							
	AND							
	Patient must be participating in a four week trial of tobramycin inhalation powder and will be assessed for ability to tolerate the dry powder formulation in order to qualify for continued PBS-subsidised therapy. The trial commencement date must be documented in the patient's medical records.							
	Population criteria:							
	Patient must be 6 years of age or older.							
	Note							
	No increase in the maximum quantity or number of units may be authorised.							
	Note							
	No increase in the maximum number of repeats may be authorised.							
	Note							
	Special Pricing Arrangements apply.							
10066T	tobramycin 28 mg inhalation, 224 capsules	1	..	..	2549.70	37.70	TOBI podhaler	NV
	TOBRAMYCIN							
	Authority required (STREAMLINED)							
	4513							
	Proven Pseudomonas aeruginosa infection							
	Treatment Phase: Continuing treatment							
	Clinical criteria:							
	Patient must have cystic fibrosis,							
	AND							
	Patient must have previously been issued with an authority prescription for tobramycin inhalation capsules,							
	AND							
	Patient must have demonstrated ability to tolerate the dry powder formulation following the initial 4-week treatment period, as agreed by the patient, the patient's family (in the case of paediatric patients) and the treating physician(s).							
	Population criteria:							
	Patient must be 6 years of age or older.							
	Note							
	No increase in the maximum quantity or number of units may be authorised.							
	Note							
	No increase in the maximum number of repeats may be authorised.							
	Note							
	Special Pricing Arrangements apply.							
10074F	tobramycin 28 mg inhalation, 224 capsules	1	2	..	2549.70	37.70	TOBI podhaler	NV
	TOBRAMYCIN							
	Authority required (STREAMLINED)							
	3842							
	Management of a proven Pseudomonas aeruginosa infection in a patient with cystic fibrosis							
	Note							
	No applications for increased maximum quantities and/or repeats will be authorised.							
	Note							
	Special Pricing Arrangements apply.							
5442K	tobramycin 300 mg/5 mL inhalation: solution, 56 x 5 mL ampoules	1	2	..	2137.70	37.70	Tobi	NV
	TOBRAMYCIN							
	Restricted benefit							

ANTIINFECTIVES FOR SYSTEMIC USE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
Systemic treatment of Pseudomonas aeruginosa infection in a patient with cystic fibrosis								
9480Y NP	tobramycin 500 mg/5 mL injection, 10 x 5 mL vials	1	1	..	357.71	37.70	Tobra-Day	PL
TOBRAMYCIN								
<u>Restricted benefit</u>								
Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent								
<u>Restricted benefit</u>								
Septicaemia, suspected								
<u>Restricted benefit</u>								
Septicaemia, proven								
1356J NP	tobramycin 80 mg/2 mL injection, 5 x 2 mL vials	2	1	..	*65.36	37.70	Hospira Pty Limited	HH
8872Y NP	tobramycin Injection 80 mg (base) in 2 mL (without preservative), 5	2	1	..	*65.36	37.70	Pfizer Australia Pty Ltd	PF

QUINOLONE ANTIBACTERIALS

Fluoroquinolones

CIPROFLOXACIN

Authority required

Respiratory tract infection proven or suspected to be caused by Pseudomonas aeruginosa in severely immunocompromised patients

Authority required

Bacterial gastroenteritis in severely immunocompromised patients

Authority required

Treatment of infections proven to be due to Pseudomonas aeruginosa or other gram-negative bacteria resistant to all other oral antimicrobials

Authority required

Treatment of joint and bone infections, epididymo-orchitis, prostatitis or perichondritis of the pinna, suspected or proven to be caused by gram-negative bacteria or gram-positive bacteria resistant to all other appropriate antimicrobials

Authority required

Gonorrhoea

1208N NP	ciprofloxacin 250 mg tablet, 14	1	..	..	12.21	13.36	^a C-Flox 250	AL
							^a Ciprofloxacin-DRLA	RZ
							^a Ciprofloxacin Sandoz	SZ
							^a Ciprol 250	QA
							^a GenRx Ciprofloxacin	GX
				^B 1.42	13.63	13.36	^a Ciproxin 250	BN

CIPROFLOXACIN

Authority required

Respiratory tract infection proven or suspected to be caused by Pseudomonas aeruginosa in severely immunocompromised patients

Authority required

Bacterial gastroenteritis in severely immunocompromised patients

Authority required

Treatment of infections proven to be due to Pseudomonas aeruginosa or other gram-negative bacteria resistant to all other oral antimicrobials

Authority required

Treatment of joint and bone infections, epididymo-orchitis, prostatitis or perichondritis of the pinna, suspected or proven to be caused by gram-negative bacteria or gram-positive bacteria resistant to all other appropriate antimicrobials

1209P NP	ciprofloxacin 500 mg tablet, 14	1	..	..	17.42	18.57	^a C-Flox 500	AL
							^a Cifran	RA
							^a Ciprofloxacin 500	CR
							^a Ciprofloxacin AN	EA
							^a Ciprofloxacin-BW	GQ
							^a Ciprofloxacin-DRLA	RZ
							^a Ciprofloxacin-GA	GN
							^a Ciprofloxacin Sandoz	SZ
							^a Ciprol 500	QA
							^a GenRx Ciprofloxacin	GX
							^a Loxip 500	DO
				^B 1.40	18.82	18.57	^a Ciproxin 500	BN

ANTIINFECTIVES FOR SYSTEMIC USE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
1210Q NP	ciprofloxacin 750 mg tablet, 14	1	..	..	22.84	23.99	^a C-Flox 750	AL
							^a Cifran	RA
							^a Ciprofloxacin 750	CR
							^a Ciprofloxacin AN	EA
							^a Ciprofloxacin-BW	GQ
							^a Ciprofloxacin-DRLA	RZ
							^a Ciprofloxacin-GA	GN
							^a Ciprofloxacin Sandoz	SZ
							^a Ciprol 750	QA
							^a GenRx Ciprofloxacin	GX
							^a Loxip 750	DO
				^B 0.40	23.24	23.99	^a Ciproxin 750	BN

NORFLOXACIN

Authority required

Acute bacterial enterocolitis

Authority required

Complicated urinary tract infection

3010K NP	norfloxacin 400 mg tablet, 14	1	1	..	11.38	12.53	^a GenRx Norfloxacin	GX
							^a Norfloxacin AN	EA
							^a Norfloxacin-GA	GN
							^a Norfloxacin Sandoz	SZ
							^a Nufloxib	AF
							^a Roxin	QA

OTHER ANTIBACTERIALS

Glycopeptide antibacterials

VANCOMYCIN

Restricted benefit

Prophylaxis of endocarditis in patients hypersensitive to penicillin

2269K	vancomycin 1 g injection, 1 x 1 g vial	1	..	..	10.76	11.91	^a Hospira Pty Limited	HH
							^a Vancomycin Alphapharm	AF
							^a Vancomycin Sandoz	SZ
							^a Vycin IV	GN
5083M DP	vancomycin 1 g injection, 1 x 1 g vial	1	..	..	10.76	11.91	^a Hospira Pty Limited	HH
							^a Vancomycin Alphapharm	AF
							^a Vancomycin Sandoz	SZ
							^a Vycin IV	GN
3130R	vancomycin 500 mg injection, 1 x 500 mg vial	2	..	..	*10.74	11.89	^a Hospira Pty Limited	HH
							^a Vancocin CP	AS
							^a Vancomycin Alphapharm	AF
							^a Vancomycin Sandoz	SZ
3323X DP	vancomycin 500 mg injection, 1 x 500 mg vial	2	..	..	*10.74	11.89	^a Hospira Pty Limited	HH
							^a Vancocin CP	AS
							^a Vancomycin Alphapharm	AF
							^a Vancomycin Sandoz	SZ

VANCOMYCIN

Restricted benefit

Endophthalmitis

Restricted benefit

Use initiated in a hospital for infections where vancomycin is an appropriate antibiotic

2270L	vancomycin 1 g injection, 1 x 1 g vial	3	..	..	*18.76	19.91	^a Hospira Pty Limited	HH

ANTIINFECTIVES FOR SYSTEMIC USE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
3131T	vancomycin 500 mg injection, 1 x 500 mg vial	5	..	..	*16.71	17.86	^a Vancomycin Alphapharm	AF
							^a Vancomycin Sandoz	SZ
							^a Vycin IV	GN
							^a Hospira Pty Limited	HH
							^a Vancocin CP	AS
							^a Vancomycin Alphapharm	AF
							^a Vancomycin Sandoz	SZ

Steroid antibacterials

FUSIDATE

Restricted benefit

For use in combination with another antibiotic in the treatment of proven serious staphylococcal infections

2312Q	fusidate sodium 250 mg tablet, 36	1	1	..	91.23	37.70	Fucidin	CS

Imidazole derivatives

METRONIDAZOLE

1636D NP	metronidazole 200 mg tablet, 21	1	1	..	8.22	9.37	^a Metrogyl 200	AF
				^B 2.30	10.52	9.37	^a Metronide 200	AV
3339R DP	metronidazole 200 mg tablet, 21	1	..	..	8.22	9.37	^a Flagyl	SW
							^a Metrogyl 200	AF
				^B 2.30	10.52	9.37	^a Metronide 200	AV
1630T NP	metronidazole 200 mg/5 mL oral liquid, 100 mL	‡1	..	..	19.16	20.31	^a Flagyl	SW
3341W DP	metronidazole 200 mg/5 mL oral liquid, 100 mL	‡1	..	..	19.16	20.31	Flagyl S	SW
1642K NP	metronidazole 500 mg suppository, 10	‡1	..	..	23.50	24.65	Flagyl	SW
5157K DP	metronidazole 500 mg suppository, 10	‡1	..	..	23.50	24.65	Flagyl	SW

METRONIDAZOLE

Restricted benefit

Treatment of anaerobic infections

1621H NP	metronidazole 400 mg tablet, 21	1	1	..	10.19	11.34	^a Metrogyl 400	AF
				^B 2.30	12.49	11.34	^a Metronide 400	AV
5155H DP	metronidazole 400 mg tablet, 21	1	..	..	10.19	11.34	^a Flagyl	SW
							^a Metrogyl 400	AF
				^B 2.30	12.49	11.34	^a Metronide 400	AV
							^a Flagyl	SW

METRONIDAZOLE

Restricted benefit

Prophylaxis to prevent infection

Clinical criteria:

Patient must be undergoing large bowel surgery.

Restricted benefit

Acute anaerobic sepsis

Treatment criteria:

Must be treated in a hospital.

Note

Pharmaceutical benefits that have the form metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags and pharmaceutical benefits that have the form metronidazole 500 mg/100 mL (0.5%) injection, 5 x 100 mL bags are equivalent for the purposes of substitution.

1821W NP	metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags	1	..	..	17.94	19.09	^a DBL Metronidazole Intravenous Infusion	HH

ANTIINFECTIVES FOR SYSTEMIC USE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							^a Metronidazole Sandoz IV	SZ
2277W NP	metronidazole 500 mg/100 mL (0.5%) injection, 5 x 100 mL bags	2	..	..	*17.94	19.09	^a Metronidazole-Clarix	AE
METRONIDAZOLE <u>Restricted benefit</u> Acute anaerobic sepsis Treatment criteria: Must be treated in a hospital. <u>Note</u> Pharmaceutical benefits that have the form metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags and pharmaceutical benefits that have the form metronidazole 500 mg/100 mL (0.5%) injection, 5 x 100 mL bags are equivalent for the purposes of substitution.								
1832K DP	metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags	1	..	..	17.94	19.09	^a DBL Metronidazole Intravenous Infusion	HH
							^a Metronidazole Sandoz IV	SZ
2298Y DP	metronidazole 500 mg/100 mL (0.5%) injection, 5 x 100 mL bags	2	..	..	*17.94	19.09	^a Metronidazole-Clarix	AE
TINIDAZOLE								
1465D NP	tinidazole 500 mg tablet, 4	1	..	..	11.13	12.28	^a Simplotan	FZ
				^b 5.41	16.54	12.28	^a Fasigyn	PF

Nitrofurantoin derivatives

NITROFURANTOIN

Caution

Nitrofurantoin may cause peripheral neuritis and severe pulmonary reactions.

1693D NP,MW	nitrofurantoin 100 mg capsule, 30	1	1	..	30.94	32.09	Macrochantin	PF
1692C NP,MW	nitrofurantoin 50 mg capsule, 30	1	1	..	24.00	25.15	Macrochantin	PF

Other antibacterials

HEXAMINE HIPPURATE

3124K NP	hexamine hippurate 1 g tablet, 100	1	5	..	46.02	37.70	Hiprex	IA

ANTIMYCOTICS FOR SYSTEMIC USE

ANTIMYCOTICS FOR SYSTEMIC USE

Triazole derivatives

FLUCONAZOLE

Authority required (STREAMLINED)

3615

Treatment of cryptococcal meningitis

Authority required (STREAMLINED)

3616

Maintenance therapy in patients with cryptococcal meningitis and immunosuppression

Authority required (STREAMLINED)

3613

Treatment of oropharyngeal candidiasis in immunosuppressed patients

Authority required (STREAMLINED)

3614

Treatment of oesophageal candidiasis in immunosuppressed patients

Authority required (STREAMLINED)

3617

Prophylaxis of oropharyngeal candidiasis in immunosuppressed patients

Authority required (STREAMLINED)

3618

Treatment of serious and life-threatening candida infections

Note

ANTIINFECTIVES FOR SYSTEMIC USE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
Shared Care Model:							
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
1472L NP	fluconazole 100 mg capsule, 28	1	5	..	44.02	37.70	^a Diflucan PF
							^a Dizole 100 AF
							^a Fluconazole Sandoz SZ
							^a Ozole RA
1473M NP	fluconazole 100 mg/50 mL injection, 1 x 50 mL vial	7	..	..	*22.51	23.66	^a Fluconazole Hexal HX
							^a Fluconazole Sandoz SZ
1475P NP	fluconazole 200 mg capsule, 28	1	5	..	76.96	37.70	^a APO-Fluconazole TX
							^a Diflucan PF
							^a Dizole 200 AF
							^a Fluconazole Sandoz SZ
							^a Fluzole 200 QA
							^a Ozole RA
1474N NP	fluconazole 200 mg/100 mL injection, 1 x 100 mL vial	7	..	..	*36.44	37.59	^a Fluconazole Alphapharm AF
							^a Fluconazole Hexal HX
							^a Fluconazole Sandoz SZ
1757L NP	fluconazole 400 mg/200 mL injection, 1 x 200 mL bag	1	..	..	13.43	14.58	Fluconazole Alphapharm AF
1471K NP	fluconazole 50 mg capsule, 28	1	5	..	26.11	27.26	^a Diflucan PF
							^a Dizole 50 AF
							^a Fluconazole Sandoz SZ
							^a Ozole RA

FLUCONAZOLE

Authority required

Treatment of cryptococcal meningitis in a patient unable to take a solid dose form of fluconazole

Authority required

Maintenance therapy in a patient with cryptococcal meningitis and immunosuppression unable to take a solid dose form of fluconazole

Authority required

Treatment of oropharyngeal candidiasis in an immunosuppressed patient unable to take a solid dose form of fluconazole

Authority required

Treatment of oesophageal candidiasis in an immunosuppressed patient unable to take a solid dose form of fluconazole

Authority required

Prophylaxis of oropharyngeal candidiasis in an immunosuppressed patient unable to take a solid dose form of fluconazole

Authority required

Treatment of serious and life-threatening candida infections in a patient unable to take a solid dose form of fluconazole

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

5446P NP	fluconazole 50 mg/5 mL oral liquid: powder for, 35 mL	1	..	..	#68.28	37.70	Diflucan PF

ITRACONAZOLE

Authority required (STREAMLINED)

3607

Systemic aspergillosis

Authority required (STREAMLINED)

3608

Systemic sporotrichosis

Authority required (STREAMLINED)

3609

Systemic histoplasmosis

Authority required (STREAMLINED)

3610

ANTIINFECTIVES FOR SYSTEMIC USE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

Treatment and maintenance therapy in patients with AIDS who have disseminated pulmonary histoplasmosis infection

Authority required (STREAMLINED)

3612

Treatment and maintenance therapy in patients with AIDS who have chronic pulmonary histoplasmosis infection

Authority required (STREAMLINED)

3613

Treatment of oropharyngeal candidiasis in immunosuppressed patients

Authority required (STREAMLINED)

3614

Treatment of oesophageal candidiasis in immunosuppressed patients

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8196J NP	itraconazole 100 mg capsule, 60	1	5	..	247.13	37.70	Sporanox	JC

POSACONAZOLE

Authority required

Treatment of invasive aspergillosis in patients intolerant to, or with disease refractory to, alternative therapy

Authority required

Treatment of fusariosis, zygomycosis, coccidioidomycosis, chromoblastomycosis and mycetoma in patients intolerant to, or with disease refractory to, alternative therapy

Authority required

Prophylaxis of invasive fungal infections, including both yeasts and moulds, in a patient who is at high risk of developing these infections, defined as follows:

(1) Neutropenia

Patients with anticipated neutropenia (an absolute neutrophil count of less than 500 cells per cubic millimetre) for at least 10 days, who are receiving chemotherapy for acute myelogenous leukaemia or myelodysplastic syndrome.

Treatment should continue until recovery of the neutrophil count to at least 500 cells per cubic millimetre.

Patients who have had a previous invasive fungal infection should have secondary prophylaxis during subsequent episodes of neutropenia.

(2) Graft versus host disease (GVHD)

Patients with acute GVHD grades II to IV or extensive chronic GVHD, who are receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant.

No more than 6 months therapy per episode will be PBS-subsidised

Note

Application for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

9360P NP	posaconazole 40 mg/mL oral liquid, 105 mL	1	..	..	733.60	37.70	Noxafil	MK

VORICONAZOLE

Authority required

Prophylaxis of invasive fungal infections including both yeasts and moulds

Clinical criteria:

Patient must be considered at high risk of developing an invasive fungal infection due to anticipated neutropenia (an absolute neutrophil count less than 500 cells per cubic millimetre) for at least 10 days whilst receiving chemotherapy for acute myeloid leukaemia or myelodysplastic syndrome; OR

Patient must be considered at high risk of developing an invasive fungal infection due to having acute graft versus host disease (GVHD) grade II, III or IV, or, extensive chronic GVHD, whilst receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant; OR

Patient must be undergoing allogeneic haematopoietic stem cell transplant using either bone marrow from an unrelated donor or umbilical cord blood (related or unrelated), and, be considered to be at high risk of developing an invasive fungal infection during the neutropenic phase prior to engraftment.

Note

For patients with graft versus host disease, acute myeloid leukaemia or myelodysplastic syndrome, applications for an increased maximum quantity

ANTIINFECTIVES FOR SYSTEMIC USE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.								
Note								
For patients undergoing allogeneic haematopoietic stem cell transplant, applications for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 2 months' treatment may be authorised.								
Note								
Shared Care Model:								
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
10198R NP	voriconazole 200 mg tablet, 56	1	..	..	2237.86	37.70	Vfend	PF
10168E NP	voriconazole 40 mg/mL oral liquid: powder for, 70 mL	1	..	..	#593.97	37.70	Vfend	PF
10173K NP	voriconazole 50 mg tablet, 56	1	..	..	591.34	37.70	Vfend	PF

VORICONAZOLE

Authority required

Definite or probable invasive aspergillosis

Treatment Phase: Treatment and maintenance therapy

Population criteria:

Patient must be immunocompromised.

Authority required

Serious fungal infections

Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

The condition must be caused by *Scedosporium* species or *Fusarium* species.

Authority required

Serious Candida infections

Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

The condition must be caused by species not susceptible to fluconazole; OR

The condition must be resistant to fluconazole; OR

Patient must not tolerate fluconazole.

Authority required

Serious invasive mycosis infections

Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

The treatment must be for invasive mycosis infections other than definite or probable invasive aspergillosis.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

9364W NP	voriconazole 200 mg tablet, 56	1	2	..	2237.86	37.70	Vfend	PF
9363T NP	voriconazole 50 mg tablet, 56	1	2	..	591.34	37.70	Vfend	PF

VORICONAZOLE

Authority required

Definite or probable invasive aspergillosis

Treatment Phase: Treatment and maintenance therapy

Population criteria:

Patient must be immunocompromised.

Authority required

Serious fungal infections

Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

ANTIINFECTIVES FOR SYSTEMIC USE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	The condition must be caused by <i>Scedosporium</i> species or <i>Fusarium</i> species.							
	Authority required							
	Serious Candida infections							
	Treatment Phase: Treatment and maintenance therapy							
	Clinical criteria:							
	The condition must be caused by species not susceptible to fluconazole; OR							
	The condition must be resistant to fluconazole; OR							
	Patient must not tolerate fluconazole.							
	Authority required							
	Serious invasive mycosis infections							
	Treatment Phase: Treatment and maintenance therapy							
	Clinical criteria:							
	The treatment must be for invasive mycosis infections other than definite or probable invasive aspergillosis.							
	Note							
	Application for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.							
	Note							
	Shared Care Model:							
	For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
9452L NP	voriconazole 40 mg/mL oral liquid: powder for, 70 mL	1	..	..	#593.97	37.70	Vfend	PF

ANTIMYCOBACTERIALS

DRUGS FOR TREATMENT OF TUBERCULOSIS

Hydrazides

ISONIAZID

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1554T NP	isoniazid 100 mg tablet, 100	1	2	..	21.83	22.98	Fawns and McAllan Proprietary Limited	FM

DRUGS FOR TREATMENT OF LEPROSIS

Drugs for treatment of leprosy

DAPSONE

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1272Y NP	dapsone 100 mg tablet, 100	1	1	..	114.18	37.70	Link Medical Products Pty Ltd	LM
8801F NP	dapsone 25 mg tablet, 100	1	1	..	100.92	37.70	Link Medical Products Pty Ltd	LM

RIFAMPICIN

Restricted benefit

Prophylaxis of meningococcal disease in close contacts and carriers

Restricted benefit

Prophylactic treatment of contacts of patients with *Haemophilus influenzae* type B

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

ANTIINFECTIVES FOR SYSTEMIC USE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
8025J NP	rifampicin 100 mg/5 mL oral liquid, 60 mL	1	..	..	30.69	31.84	Rifadin	SW
1981G NP	rifampicin 150 mg capsule, 10	1	..	..	39.12	37.70	Rimycin 150	AF
1984K NP	rifampicin 300 mg capsule, 10	1	..	..	21.53	22.68	Rimycin 300	AF
RIFAMPICIN								
<u>Authority required</u>								
Leprosy in adults								
<u>Note</u>								
Shared Care Model:								
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
1982H NP	rifampicin 150 mg capsule, 100	1	..	..	306.14	37.70	Rimycin 150	AF
1983J NP	rifampicin 300 mg capsule, 100	1	..	..	147.98	37.70	Rimycin 300	AF

ANTIVIRALS FOR SYSTEMIC USE

DIRECT ACTING ANTIVIRALS

Nucleosides and nucleotides excl. reverse transcriptase inhibitors

ACICLOVIR

Authority required (STREAMLINED)

3632

Moderate to severe initial genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is desirable but need not delay treatment

Note

Aciclovir 200 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

No applications for increased maximum quantities and/or repeats will be authorised.

Note

For item codes 1003T and 1555W, pharmaceutical benefits that have the form tablet 200 mg are equivalent for the purposes of substitution.

1003T NP	aciclovir 200 mg tablet, 25	2	..	..	*32.42	33.57	^a Acihexal	SZ
							^a Acyclo-V 200	AF
							^a Lovir	GN
				^b 2.06	*34.48	33.57	^a Zovirax 200 mg	GK
1555W NP	aciclovir 200 mg tablet, 50	1	..	..	32.43	33.58	^a GenRx Aciclovir	GX

ACICLOVIR

Authority required (STREAMLINED)

3633

Episodic treatment or suppressive therapy of moderate to severe recurrent genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment

Note

Aciclovir 200 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

1007B NP	aciclovir 200 mg tablet, 90	1	5	..	51.44	37.70	^a Aciclovir 200	CR
							^a Aciclovir GH	GQ
							^a Acyclo-V 200	AF
							^a Chem mart Aciclovir	CH
							^a GenRx Aciclovir	GX
							^a Lovir	GN
							^a Ozvir	RA
							^a Terry White Chemists Aciclovir	TW
				^b 1.49	52.93	37.70	^a Zovirax 200 mg	GK

ACICLOVIR

Authority required (STREAMLINED)

3630

ANTIINFECTIVES FOR SYSTEMIC USE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
Note No applications for repeats will be authorised.							
8002E NP	famciclovir 250 mg tablet, 21	1	..	..	59.55	37.70	a APO-Famciclovir TX a Auro-Famciclovir 250 DO a Ezovir AF a Famciclovir AN EA a Famciclovir-GA GN a Famciclovir GQ generichealth 250 a Famciclovir Sandoz SZ a Famciclovir SCP 250 CR a Famlo RA a Famvir NV a Favic 250 QA

FAMCICLOVIR

Authority required (STREAMLINED)

3623

Suppressive therapy of moderate to severe recurrent genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment

Note

Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

8217L NP	famciclovir 250 mg tablet, 56	1	5	..	147.51	37.70	a APO-Famciclovir TX a Auro-Famciclovir 250 DO a Ezovir AF a Famciclovir AN EA a Famciclovir-GA GN a Famciclovir GQ generichealth 250 a Famciclovir Sandoz SZ a Famciclovir SCP 250 CR a Famlo RA a Famvir NV a Favic 250 QA

FAMCICLOVIR

Authority required (STREAMLINED)

3625

Treatment of immunocompromised patients with herpes zoster within 72 hours of the onset of the rash

Note

Famciclovir is effective only if commenced within 72 hours of onset of rash.

Famciclovir 500 mg is not PBS-subsidised for chickenpox.

Famciclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients.

Note

No applications for repeats will be authorised.

8897G NP	famciclovir 500 mg tablet, 30	1	..	..	82.15	37.70	a APO-Famciclovir TX a Chem mart Famciclovir CH a Famciclovir AN EA a Famciclovir Sandoz SZ a Famvir NV a Favic 500 QA a Terry White Chemists TW Famciclovir

FAMCICLOVIR

Authority required (STREAMLINED)

3626

Episodic treatment or suppressive therapy of moderate to severe recurrent genital herpes in immunocompromised patients. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment

Authority required (STREAMLINED)

ANTIINFECTIVES FOR SYSTEMIC USE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
3627							
Episodic treatment of moderate to severe recurrent oral or labial herpes in a patient with HIV infection and a CD4 cell count of less than 500 million per litre. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment							
Authority required (STREAMLINED)							
3628							
Suppressive therapy of moderate to severe recurrent oral or labial herpes in a patient with HIV infection and a CD4 cell count of less than 150 million per litre. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment							
Authority required (STREAMLINED)							
3629							
Suppressive therapy of moderate to severe recurrent oral or labial herpes in a patient with HIV infection and other opportunistic infections or AIDS defining tumours. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment							
Note							
Famciclovir 500 mg is not PBS-subsidised for chickenpox.							
Famciclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients.							
8896F NP	famciclovir 500 mg tablet, 56	1	5	..	147.51	37.70	a APO-Famciclovir TX a Auro-Famciclovir 500 DO a Chem mart Famciclovir CH a Ezovir AF a Famciclovir AN EA a Famciclovir-GA GN a Famciclovir GQ generichealth 500 a Famciclovir Sandoz SZ a Famvir NV a Favic 500 QA a Terry White Chemists TW Famciclovir
VALACICLOVIR							
Authority required (STREAMLINED)							
3632							
Moderate to severe initial genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is desirable but need not delay treatment							
Note							
Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.							
Note							
No applications for increased maximum quantities and/or repeats will be authorised.							
8133C NP	valaciclovir 500 mg tablet, 10	2	..	..	*36.72	37.70	a APO-Valaciclovir TX a Chem mart Valaciclovir CH a Terry White Chemists TW Valaciclovir a Vaclovir AF a Valaciclovir Actavis VN a Valaciclovir AN EA a Valaciclovir GA GN a Valaciclovir Sandoz SZ a Valnir QA a Valtrex AS a Zelitrex UA
VALACICLOVIR							
Authority required (STREAMLINED)							
3623							
Suppressive therapy of moderate to severe recurrent genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment							
Note							
Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.							
5480K	valaciclovir 500 mg tablet, 30	1	5	..	50.35	37.70	a APO-Valaciclovir TX

ANTIINFECTIVES FOR SYSTEMIC USE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
NP							a Chem mart Valaciclovir CH a Shilova 500 DO a Terry White Chemists TW Valaciclovir a Vaclovir AF a Valaciclovir Actavis VN a Valaciclovir AN EA a Valaciclovir GA GN a Valaciclovir GQ generichealth a Valaciclovir RBX RA a Valaciclovir SZ HX a Valacor 500 CR a Valnir QA a Valtrex AS a Zelitrex UA

VALACICLOVIR

Authority required (STREAMLINED)

3624

Episodic treatment of moderate to severe recurrent genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment

Note

Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

8134D	valaciclovir 500 mg tablet, 30	1	5	..	50.35	37.70	a APO-Valaciclovir TX a Chem mart Valaciclovir CH a Shilova 500 DO a Terry White Chemists TW Valaciclovir a Vaclovir AF a Valaciclovir Actavis VN a Valaciclovir AN EA a Valaciclovir GA GN a Valaciclovir GQ generichealth a Valaciclovir RBX RA a Valaciclovir Sandoz SZ a Valaciclovir SZ HX a Valacor 500 CR a Valnir QA a Valtrex AS a Zelitrex UA
NP							

VALACICLOVIR

Authority required (STREAMLINED)

3622

Treatment of patients with herpes zoster within 72 hours of the onset of the rash

Authority required (STREAMLINED)

3631

Herpes zoster ophthalmicus

Note

Valaciclovir is effective only if commenced within 72 hours of onset of rash.

Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

Note

No applications for repeats will be authorised.

8064K	valaciclovir 500 mg tablet, 42	1	..	..	66.96	37.70	a APO-Valaciclovir TX a Chem mart Valaciclovir CH a Terry White Chemists TW Valaciclovir a Vaclovir AF a Valaciclovir Actavis VN
NP							

ANTIINFECTIVES FOR SYSTEMIC USE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							a Valaciclovir AN	EA
							a Valaciclovir GA	GN
							a Valaciclovir generichealth	GQ
							a Valaciclovir RBX	RA
							a Valaciclovir Sandoz	SZ
							a Valacor 500	CR
							a Valnir	QA
							a Valtrex	AS
							a Zelitrex	UA

VACCINES

BACTERIAL VACCINES

Pneumococcal vaccines

PNEUMOCOCCAL PURIFIED CAPSULAR POLYSACCHARIDES

Restricted benefit

Splenectomised persons over 2 years of age

Restricted benefit

Persons with Hodgkin's disease

Restricted benefit

Persons at high risk of pneumococcal infections

10210J NP	pneumococcal purified capsular polysaccharides 25 microgram/0.5 mL injection, 1 x 0.5 mL syringe	1	..	..	49.02	37.70	Pneumovax 23	CS
1903E NP	pneumococcal purified capsular polysaccharides 25 microgram/0.5 mL injection, 1 x 0.5 mL vial	1	..	..	49.02	37.70	Pneumovax 23	CS

Tetanus vaccines

DIPHTHERIA TOXOID + TETANUS TOXOID

Note

For immunisation of adults and children aged greater than or equal to 8 years.

8783G NP	diphtheria toxoid 2 international units/0.5 mL + tetanus toxoid 20 international units/0.5 mL injection, 5 x 0.5 mL syringes	1	..	..	75.68	37.70	ADT Booster	CS

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

ANTINEOPLASTIC AGENTS

ALKYLATING AGENTS

Nitrogen mustard analogues

CHLORAMBUCIL								
1163F	chlorambucil 2 mg tablet, 25	4	2	..	*154.12	37.70	Leukeran	AS
CYCLOPHOSPHAMIDE								
10026Q	cyclophosphamide 50 mg tablet, 50	1	2	..	83.64	37.70	Endoxan	BX
1266P	cyclophosphamide 50 mg tablet, 50	1	2	..	31.63	32.78	Cycloblastin	ZX
MELPHALAN								
2547C	melfhalan 2 mg tablet, 25	1	1	..	77.11	37.70	Alkeran	AS

Alkyl sulfonates

BUSULFAN								
1128J	busulfan 2 mg tablet, 100	1	..	..	96.18	37.70	Myleran	AS

Nitrosoureas

CARMUSTINE

Restricted benefit

Glioblastoma multiforme, suspected or confirmed, at the time of initial surgery

Note

Carmustine is not PBS-subsidised for use in conjunction with PBS-subsidised temozolomide.

8898H	carmustine 7.7 mg implant, 8	1	..	..	17539.66	37.70	Gliadel	OA

Other alkylating agents

TEMOZOLOMIDE								
8380C	temozolomide 100 mg capsule, 5	1	5	..	357.50	37.70	^a Astromide	GN
							^a Orion Temozolomide	ON
							^a Temizole 100	QA
							^a Temodal	MK
							^a Temozolomide Alphapharm	AF
9362R	temozolomide 140 mg capsule, 5	1	5	..	474.86	37.70	^a Temozolomide AN	EA
							^a Astromide	GN
							^a Orion Temozolomide	ON
							^a Temizole 140	QA
							^a Temodal	MK
							^a Temozolomide Alphapharm	AF
2438H	temozolomide 180 mg capsule, 5	1	5	..	593.35	37.70	^a Temozolomide AN	EA
							^a Astromide	GN
8379B	temozolomide 20 mg capsule, 5	1	5	..	92.20	37.70	^a Orion Temozolomide	ON
							^a Temodal	MK
							^a Astromide	GN
							^a Orion Temozolomide	ON
							^a Temizole 20	QA
							^a Temodal	MK
							^a Temozolomide	AF

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
8381D	temozolomide 250 mg capsule, 5	1	5	..	828.94	37.70	Alphapharm	
							Temozolomide AN	EA
							Astromide	GN
							Orion Temozolomide	ON
							Temizole 250	QA
8378Y	temozolomide 5 mg capsule, 5	1	5	..	37.14	37.70	Temodal	MK
							Temozolomide	AF
							Alphapharm	
							Temozolomide AN	EA
							Astromide	GN
							Orion Temozolomide	ON
							Temizole 5	QA
							Temodal	MK
							Temozolomide	AF
							Alphapharm	
8821G	temozolomide 100 mg capsule, 5	3	2	..	*1044.91	37.70	Temozolomide AN	EA
							Astromide	GN
							Orion Temozolomide	ON
							Temizole 100	QA
							Temodal	MK
							Temozolomide	AF
							Alphapharm	
							Temozolomide AN	EA
							Astromide	GN
							Orion Temozolomide	ON
9361Q	temozolomide 140 mg capsule, 5	3	2	..	*1411.06	37.70	Temizole 140	QA
							Temodal	MK
							Temozolomide	AF
							Alphapharm	
							Temozolomide AN	EA
10062N	temozolomide 180 mg capsule, 5	3	2	..	*1766.53	37.70	Astromide	GN
							Orion Temozolomide	ON
							Temizole 140	QA
							Temodal	MK
							Temozolomide	AF
8820F	temozolomide 20 mg capsule, 5	3	2	..	*257.77	37.70	Alphapharm	
							Temozolomide AN	EA
							Astromide	GN
							Orion Temozolomide	ON
							Temizole 20	QA
8819E	temozolomide 5 mg capsule, 5	3	2	..	*93.94	37.70	Temodal	MK
							Temozolomide	AF
							Alphapharm	
							Temozolomide AN	EA
							Astromide	GN
							Orion Temozolomide	ON
							Temizole 5	QA
							Temodal	MK
							Temozolomide	AF
							Alphapharm	

TEMOZOLOMIDE

Restricted benefit

Glioblastoma multiforme

Treatment criteria:

Patient must be undergoing concomitant radiotherapy.

Note

Temozolomide is not PBS-subsidised for use in conjunction with PBS-subsidised carmustine.

Note

No increase in the maximum number of repeats may be authorised.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							^a Temozolomide AN	EA
ANTIMETABOLITES								
<i>Folic acid analogues</i>								
METHOTREXATE								
<u>Note</u>								
For item codes 2395C and 1818Q, pharmaceutical benefits that have the form injection 50 mg in 2 mL are equivalent for the purposes of substitution.								
1818Q	METHOTREXATE Injection 50 mg in 2 mL, 1	5	5	..	*19.71	20.86	^a Methaccord	GN
2395C	methotrexate 50 mg/2 mL injection, 5 x 2 mL vials	1	5	..	19.69	20.84	^a Methotrexate MYX ^a Hospira Pty Limited	YN HH
METHOTREXATE								
2272N	methotrexate 10 mg tablet, 15	1	3	..	20.68	21.83	Methoblastin	PF
1622J	methotrexate 2.5 mg tablet, 30	1	5	..	13.46	14.61	^a Hospira Pty Limited	HH
2396D	methotrexate 5 mg/2 mL injection, 5 x 2 mL vials	1	..	..	19.93	21.08	^a Methoblastin ^a Hospira Pty Limited	PF HH
METHOTREXATE								
<u>Restricted benefit</u>								
For patients requiring doses greater than 20 mg per week								
1623K	methotrexate 10 mg tablet, 50	1	2	..	51.58	37.70	Methoblastin	PF
<i>Purine analogues</i>								
FLUDARABINE								
9184J	fludarabine phosphate 10 mg tablet, 20	1	5	..	937.04	37.70	Fludara	GZ
MERCAPTOPURINE								
10214N	mercaptopurine 20 mg/mL oral liquid, 100 mL	‡1	2	..	462.37	37.70	Allmercap	LM
1598D	mercaptopurine 50 mg tablet, 25	4	2	..	*267.12	37.70	Purinethol	AS
THIOGUANINE								
1233X	thioguanine 40 mg tablet, 25	1	1	..	243.21	37.70	Lanvis	AS
<i>Pyrimidine analogues</i>								
CAPECITABINE								
8361C	capecitabine 150 mg tablet, 60	1	2	..	105.47	37.70	^a Capecitabine Actavis	GN
							^a Capecitabine Alphapharm	AF
							^a Capecitabine AN	EA
							^a Capecitabine-DRLA	RZ
							^a Capecitabine Sandoz	SZ
							^a Xelabine	QA
							^a Xeloda	RO
8362D	capecitabine 500 mg tablet, 120	1	2	..	585.31	37.70	^a Capecitabine Actavis	GN
							^a Capecitabine Alphapharm	AF
							^a Capecitabine AN	EA
							^a Capecitabine Apotex	TX
							^a Capecitabine-DRLA	RZ
							^a Capecitabine GH	GQ
							^a Capecitabine Sandoz	SZ

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							^a Xelabine	QA
							^a Xeloda	RO

PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS

Vinca alkaloids and analogues

VINORELBINE

Authority required

Advanced breast cancer

Clinical criteria:

Patient must have failed standard prior therapy, which includes an anthracycline.

Authority required

Locally advanced or metastatic non-small cell lung cancer

9009E	vinorelbine 20 mg capsule, 1	20	2	..	*1579.56	37.70	Navelbine	FB
9010F	vinorelbine 30 mg capsule, 1	16	2	..	*1887.56	37.70	Navelbine	FB

Podophyllotoxin derivatives

ETOPOSIDE

1389D	etoposide 100 mg capsule, 10	1	..	..	391.07	37.70	Vepesid	BQ
1396L	etoposide 50 mg capsule, 20	1	..	..	445.28	37.70	Vepesid	BQ

CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

Anthracyclines and related substances

IDARUBICIN

Restricted benefit

Acute myelogenous leukaemia

2448W	idarubicin hydrochloride 10 mg capsule, 1	3	..	..	*494.83	37.70	Zavedos	PF
2446R	idarubicin hydrochloride 5 mg capsule, 1	3	..	..	*267.94	37.70	Zavedos	PF

OTHER ANTINEOPLASTIC AGENTS

Protein kinase inhibitors

DABRAFENIB

Authority required

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

Clinical criteria:

The treatment must be the sole PBS-subsidised therapy for this condition,

AND

Patient must have previously been issued with an authority prescription for this drug,

AND

Patient must have stable or responding disease.

Note

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

Note

A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
No increase in the maximum number of repeats may be authorised.								
Note								
Special Pricing Arrangements apply.								
2954L	dabrafenib 50 mg capsule, 120	1	5	..	5888.15	37.70	Tafinlar	GK
10003L	dabrafenib 75 mg capsule, 120	1	5	..	8758.87	37.70	Tafinlar	GK

DABRAFENIB

Authority required

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

Clinical criteria:

The treatment must be the sole PBS-subsidised therapy for this condition,

AND

The condition must be positive for a BRAF V600 mutation,

AND

The condition must not have been treated previously with PBS subsidised therapy; OR

Patient must have developed intolerance to another BRAF inhibitor of a severity necessitating permanent treatment withdrawal,

AND

Patient must have a WHO performance status of 2 or less.

Note

A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

Special Pricing Arrangements apply.

2963Y	dabrafenib 50 mg capsule, 120	1	3	..	5888.15	37.70	Tafinlar	GK
2846T	dabrafenib 75 mg capsule, 120	1	3	..	8758.87	37.70	Tafinlar	GK

DASATINIB

Authority required

Initial treatment, as the sole PBS-subsidised therapy, of a patient in the chronic phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, BCR-ABL tyrosine kinase, and who has a primary diagnosis of chronic myeloid leukaemia.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.

Patients should be commenced on a dose of dasatinib of at least 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to dasatinib therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Chronic Myeloid Leukaemia - Chronic Phase, First Line - Supporting Information form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow; and

(4) a signed patient acknowledgement form

Authority required

Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial PBS-subsidised treatment with dasatinib for the chronic phase of chronic myeloid leukaemia and who has demonstrated either a major cytogenetic response or less than 1% BCR-ABL level in the blood.

[illegible]

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	6. Definitions of response.							
	A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.							
	A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.							
	7. Definitions of loss of response.							
	Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy.							
	Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.							
1416M	dasatinib 100 mg tablet, 30	1	5	..	5004.14	37.70	Sprycel	BQ
1354G	dasatinib 20 mg tablet, 60	1	5	..	3095.79	37.70	Sprycel	BQ
1381Q	dasatinib 50 mg tablet, 60	1	5	..	5004.14	37.70	Sprycel	BQ
1415L	dasatinib 70 mg tablet, 60	1	5	..	6160.53	37.70	Sprycel	BQ

DASATINIB

Authority required

Initial treatment, as the sole PBS-subsidised therapy, of a patient with chronic myeloid leukaemia in any disease phase who has failed an adequate trial of imatinib or nilotinib as first-line treatment.

Failure of an adequate trial of imatinib or nilotinib is defined as:

(i) Lack of response to initial imatinib or nilotinib therapy, defined as either:

— failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or nilotinib for patients initially treated in chronic phase; or

— failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or nilotinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or

— failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or nilotinib; OR

(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or nilotinib therapy; OR

(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or nilotinib therapy; OR

(iv) Development of accelerated phase or blast crisis in a patient previously prescribed imatinib or nilotinib for any phase of chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

(3) Peripheral basophils greater than or equal to 20%; or

(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR

Blast crisis is defined as either:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or

(2) Extramedullary involvement other than spleen and liver; OR

(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.

Patients should be commenced on a dose of dasatinib of at least 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to dasatinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals.

Applications for authorisation must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Chronic Myeloid Leukaemia - Second and Third Line - Supporting Information Form; and

(c) a signed patient acknowledgement; and

(d) a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale. (The date of the relevant pathology report needs to be provided); and

(e) where there has been a loss of response to imatinib or nilotinib, a copy of the current confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement

Authority required

Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial PBS-subsidised treatment with dasatinib for chronic myeloid leukaemia, and who has demonstrated either a major cytogenetic response, or less than 1% BCR-ABL level in the blood, to dasatinib in the preceding 18 months and thereafter at 12 monthly intervals.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Chronic Myeloid Leukaemia - Second and Third Line - Application Form for continuing treatment; and
- (3) demonstration of continued response to treatment as evidenced by either:

(a) major cytogenetic response [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided; or

(b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided

Note

Any queries concerning the arrangements to prescribe dasatinib may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Applications for authority to prescribe dasatinib should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib. Imatinib mesylate is not approved for use in second or third line treatment.

Patients are eligible for PBS-subsidised treatment with only one of dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent.

Nilotinib is not approved for patients in blast crisis.

1. Initial second line treatment

From 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib within the initial 18 month treatment period as second-line therapy, as long as only one agent is approved at a time and providing the patient did not fail that drug as first-line therapy.

During the initial 18 month treatment period, switching between approved second-line agents may only occur for reasons of intolerance, not failure of response.

2. Initial third line treatment

Third-line treatment with a TKI can only be approved when imatinib is used for first-line treatment. Patients will only be approved for PBS-subsidised treatment with one third-line agent.

From 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib providing the patient did not fail that drug as first or second line therapy and for nilotinib the patient is not in blast crisis.

3. Continuing treatment for second and third line treatment

All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows:

(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and

(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

During second line continuing treatment beyond the initial 18 month treatment period, switching between approved second line TKI agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of a third line agent.

4. Authority approval requirements.

Response criteria to initial treatment with dasatinib or nilotinib:

For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent). 5. Definitions of response. A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response. 6. Definitions of loss of response. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.							
9342Q	dasatinib 100 mg tablet, 30	1	5	..	5004.14	37.70	Sprycel	BQ
2478K	dasatinib 20 mg tablet, 60	1	5	..	3095.79	37.70	Sprycel	BQ
2482P	dasatinib 50 mg tablet, 60	1	5	..	5004.14	37.70	Sprycel	BQ
2485T	dasatinib 70 mg tablet, 60	1	5	..	6160.53	37.70	Sprycel	BO

DASATINIB

Authority required

Initial treatment, as monotherapy, of a patient with acute lymphoblastic leukaemia (ALL) bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL, who has failed treatment with chemotherapy AND imatinib and where appropriate, allogeneic haemopoietic stem cell transplantation.

Failure of treatment is defined as either:

- (i) Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with intensive chemotherapy and imatinib;
- (ii) Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by chemotherapy and imatinib;
- (iii) Morphological or cytogenetic relapse or persistence of leukaemia after allogeneic haemopoietic stem cell transplantation.

Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells bearing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.

The first authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and
- (c) a signed patient acknowledgement; and
- (d) a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. The date of the relevant pathology report(s) need(s) to be provided

Authority required

Initial treatment, as monotherapy, of a patient with acute lymphoblastic leukaemia bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL, who has been treated prior to 1 December 2007 and has failed treatment with chemotherapy and where appropriate, allogeneic haemopoietic stem cell transplantation.

Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells bearing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.

The first authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and
- (c) a signed patient acknowledgement; and
- (d) a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. The date of the relevant pathology report(s) need(s) to be provided

Authority required

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Continuing treatment, as monotherapy, of a patient with acute lymphoblastic leukaemia bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL, where the patient has previously been issued with an authority prescription for dasatinib and does not have progressive disease.							
	Authority applications for continuing treatment may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)							
	Note							
	Any queries concerning the arrangements to prescribe dasatinib may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).							
	Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au .							
	Applications for authority to prescribe dasatinib should be forwarded to:							
	Medicare Australia							
	Prior Written Approval of Specialised Drugs							
	Reply Paid 9826							
	GPO Box 9826							
	HOBART TAS 7001							
	Note							
	Dasatinib will only be subsidised for patients with acute lymphoblastic leukaemia who are not receiving concomitant PBS-subsidised imatinib mesylate and who are not appropriate for an allogeneic haemopoietic stem cell transplant.							
	Note							
	No applications for increased repeats will be authorised.							
9343R	dasatinib 100 mg tablet, 30	1	2	..	5004.14	37.70	Sprycel	BQ
9125G	dasatinib 20 mg tablet, 60	1	2	..	3095.79	37.70	Sprycel	BQ
9126H	dasatinib 50 mg tablet, 60	1	2	..	5004.14	37.70	Sprycel	BQ
9127J	dasatinib 70 mg tablet, 60	1	2	..	6160.53	37.70	Sprycel	BQ

ERLOTINIB

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

Clinical criteria:

The treatment must be as monotherapy,

AND

Patient must have previously been issued with an authority prescription for this drug prior to 1 August 2014,

AND

Patient must not have progressive disease.

Population criteria:

Patient must have a wild type epidermal growth factor receptor (EGFR) gene; OR

Patient must have an epidermal growth factor receptor (EGFR) gene of unknown type.

10019H	erlotinib 100 mg tablet, 30	1	3	..	1239.13	37.70	Tarceva	RO
10025P	erlotinib 150 mg tablet, 30	1	3	..	1514.10	37.70	Tarceva	RO
10028T	erlotinib 25 mg tablet, 30	1	3	..	355.07	37.70	Tarceva	RO

ERLOTINIB

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

Clinical criteria:

The treatment must be as monotherapy,

AND

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, AND Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal, AND Patient must have a WHO performance status of 2 or less. Population criteria: Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material. Authority required Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Treatment Phase: Continuing treatment Clinical criteria: The treatment must be as monotherapy, AND Patient must have previously been issued with an authority prescription for this drug, AND Patient must not have progressive disease. Population criteria: Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.								
10020J	erlotinib 100 mg tablet, 30	1	3	..	1239.13	37.70	Tarceva	RO
10014C	erlotinib 150 mg tablet, 30	1	3	..	1514.10	37.70	Tarceva	RO
10022L	erlotinib 25 mg tablet, 30	1	3	..	355.07	37.70	Tarceva	RO

EVEROLIMUS

Authority required

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have progressive disease according to the Response Evaluation Criteria In Solid Tumours (RECIST) following first-line treatment with a tyrosine kinase inhibitor,

AND

Patient must have a WHO performance status of 2 or less,

AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised everolimus.

Patients who have progressive disease with everolimus are no longer eligible for PBS-subsidised everolimus.

Note

Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Special Pricing Arrangements apply.							
	<u>Authority required</u>							
	Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)							
	Treatment Phase: Initial treatment							
	Clinical criteria:							
	Patient must be symptomatic (despite somatostatin analogues); OR							
	Patient must have disease progression,							
	AND							
	The treatment must be as monotherapy.							
	Disease progression must be documented in the patient's medical records.							
	Patients who have developed progressive disease on sunitinib are not eligible to receive PBS-subsidised everolimus.							
	Patients who have developed intolerance to sunitinib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised everolimus.							
	<u>Note</u>							
	No increase in the maximum quantity or number of units may be authorised.							
	<u>Note</u>							
	No increase in the maximum number of repeats may be authorised.							
	<u>Note</u>							
	Special Pricing Arrangements apply.							
10132G	everolimus 10 mg tablet, 30	1	2	..	5546.70	37.70	Afinitor	NV
10133H	everolimus 5 mg tablet, 30	1	2	..	2846.70	37.70	Afinitor	NV

EVEROLIMUS

Authority required

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug for this condition,

AND

Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST),

AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Patients who have progressive disease with everolimus are no longer eligible for PBS-subsidised everolimus.

Note

Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

Special Pricing Arrangements apply.

Authority required

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug,

AND

Patient must not have disease progression,

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	AND							
	The treatment must be as monotherapy.							
	Patients who have progressive disease with this drug are no longer eligible for PBS-subsidised treatment with this drug.							
	<u>Note</u>							
	No increase in the maximum quantity or number of units may be authorised.							
	<u>Note</u>							
	No increase in the maximum number of repeats may be authorised.							
	<u>Note</u>							
	Special Pricing Arrangements apply.							
10135K	everolimus 10 mg tablet, 30	1	5	..	5546.70	37.70	Afinitor	NV
10131F	everolimus 5 mg tablet, 30	1	5	..	2846.70	37.70	Afinitor	NV
	EVEROLIMUS							
	<u>Authority required</u>							
	Tuberous sclerosis complex (TSC)							
	Treatment Phase: Initial treatment							
	Clinical criteria:							
	The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR							
	The condition must be visceral tumours associated with TSC,							
	AND							
	The treatment must be the sole PBS-subsidised therapy for this condition,							
	AND							
	Patient must not be a candidate for curative surgical resection.							
	<u>Note</u>							
	Special Pricing Arrangements apply.							
	<u>Authority required</u>							
	Tuberous sclerosis complex (TSC)							
	Treatment Phase: Continuing treatment							
	Clinical criteria:							
	The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR							
	The condition must be visceral tumours associated with TSC,							
	AND							
	The treatment must be the sole PBS-subsidised therapy for this condition,							
	AND							
	Patient must have previously been treated with PBS-subsidised everolimus for this condition,							
	AND							
	Patient must have demonstrated a response to prior treatment.							
	<u>Note</u>							
	Special Pricing Arrangements apply.							
	<u>Authority required</u>							
	Metastatic (Stage IV) breast cancer							
	Clinical criteria:							
	The condition must be hormone receptor positive,							
	AND							
	The condition must be human epidermal growth factor receptor 2 (HER2) negative,							
	AND							
	The condition must have acquired endocrine resistance as demonstrated by initial response and then recurrence or progression of disease after treatment with letrozole or anastrozole,							
	AND							
	The treatment must be in combination with exemestane.							
	Population criteria:							

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	

Patient must not be pre-menopausal.

Note

Patients who have progressive disease with everolimus are no longer eligible for PBS-subsidised everolimus.

Note

Special Pricing Arrangements apply.

2985D	everolimus 10 mg tablet, 30	1	5	..	5546.70	37.70	Afinitor	NV
2819J	everolimus 5 mg tablet, 30	1	5	..	2846.70	37.70	Afinitor	NV

EVEROLIMUS

Authority required

Tuberous sclerosis complex (TSC)

Treatment Phase: Initial treatment

Clinical criteria:

The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR

The condition must be visceral tumours associated with TSC,

AND

The treatment must be the sole PBS-subsidised therapy for this condition,

AND

Patient must not be a candidate for curative surgical resection.

Authority required

Tuberous sclerosis complex (TSC)

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR

The condition must be visceral tumours associated with TSC,

AND

The treatment must be the sole PBS-subsidised therapy for this condition,

AND

Patient must have previously been treated with PBS-subsidised everolimus for this condition,

AND

Patient must have demonstrated a response to prior treatment.

Note

Special Pricing Arrangements apply.

2818H	everolimus 2.5 mg tablet, 30	1	5	..	1483.50	37.70	Afinitor	NV

GEFITINIB

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

Clinical criteria:

The treatment must be as monotherapy,

AND

The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC,

AND

Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR

Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal,

AND

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	Patient must have a WHO performance status of 2 or less.						
	Population criteria:						
	Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.						
	<u>Authority required</u>						
	Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)						
	Treatment Phase: Continuing treatment						
	Clinical criteria:						
	The treatment must be as monotherapy,						
	AND						
	Patient must have previously been issued with an authority prescription for this drug,						
	AND						
	Patient must not have progressive disease.						
8769M	gefitinib 250 mg tablet, 30	1	3	..	1514.10	37.70	Iressa
							AP

IMATINIB

Authority required

Gastrointestinal stromal tumour

Treatment Phase: Initial treatment

Clinical criteria:

The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST),

AND

Patient must be at high risk of recurrence following complete surgical resection of primary GIST,

AND

The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining,

AND

The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy).

Applications for authorisation of initial treatment must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in Adjuvant Treatment of Gastrointestinal Stromal Tumour - Supporting Information Form which includes the following:
 - (i) a copy of a pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining; and
 - (ii) a copy of the pathology report must include the size and mitotic rate of the tumour, and the date of tumour resection must be documented, which must not be more than 3 months prior to the date of this application.

High risk of recurrence is defined as:

Primary GIST greater than 5 cm with a mitotic count of greater than 5/50 high power fields (HPF); or

Primary GIST greater than 10 cm with any mitotic rate; or

Primary GIST with a mitotic count of greater than 10/50 HPF.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

Any queries concerning patients who are enrolled on the Imatinib Compassionate Program may be directed to the Department of Human Services on 1800 700 270.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	<u>Authority required</u> Gastrointestinal stromal tumour Treatment Phase: Continuing treatment Clinical criteria: The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST), AND Patient must be at high risk of recurrence following complete surgical resection of primary GIST, AND The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy), AND Patient must have previously been issued with an authority prescription for imatinib for adjuvant treatment following complete resection of primary GIST. Applications for continuing therapy may be made by telephone.							
	<u>Note</u> Authority approval for continuing treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).							
	<u>Note</u> Written applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001							
5443L	imatinib 100 mg tablet, 60	1	5	..	1963.21	37.70	Glivec	NV
5444M	imatinib 400 mg tablet, 30	1	5	..	3779.71	37.70	Glivec	NV

IMATINIB

Authority required

Initial PBS-subsidised treatment, for up to 3 months, of a patient with a metastatic or unresectable malignant gastrointestinal stromal tumour which has been histologically confirmed by the detection of CD117 on immunohistochemical staining.

Patients must commence treatment at a dose not exceeding 400 mg per day for at least 3 months. Authority prescriptions for a higher dose will not be approved during this initial 3 month treatment period.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in the Treatment of Metastatic or Unresectable Gastrointestinal Stromal Tumour - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) a copy of a pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining; and
 - (ii) a copy of the most recent (within 2 months of the application) computed tomography (CT) scan, magnetic resonance imaging (MRI) or ultrasound assessment of the tumour(s), including whether or not there is evidence of metastatic disease; and
 - (iii) where the application for authority to prescribe is being sought on the basis of an unresectable tumour, written evidence in support of that claim must be provided

Authority required

Continuing PBS-subsidised treatment, at a dose of up to 600 mg per day, of a patient with a metastatic or unresectable malignant gastrointestinal stromal tumour who has previously been issued with an authority prescription for this drug.

Applications for continuing treatment may be made by telephone (1800 700 270, hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib

Note

Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe imatinib mesylate should be forwarded to:

Medicare Australia

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Prior Written Approval of Specialised Drugs							
	Reply Paid 9826							
	GPO Box 9826							
	HOBART TAS 7001							
	For the following diseases, written authority is required at initiation and for continuation:							
	Dermatofibrosarcoma protuberans;							
	Hypereosinophilic syndrome;							
	Chronic eosinophilic leukaemia;							
	Myelodysplastic or myeloproliferative disorder;							
	Aggressive systemic mastocytosis with eosinophilia.							
	<u>Note</u>							
	Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.							
	A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)							
	<u>Note</u>							
	No applications for increased repeats will be authorised.							
9111M	imatinib 100 mg tablet, 60	1	2	..	1963.21	37.70	Glivec	NV
9112N	imatinib 400 mg tablet, 30	1	2	..	3779.71	37.70	Glivec	NV

IMATINIB

Authority required

Initial treatment, as the sole PBS-subsidised therapy, of a patient in the chronic phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, BCR-ABL tyrosine kinase, and who has a primary diagnosis of chronic myeloid leukaemia.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.

Patients should be commenced on a dose of imatinib mesylate of 400 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to imatinib mesylate therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Chronic Myeloid Leukaemia - Chronic Phase, First Line - Supporting Information form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
- (3) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow; and
- (4) a signed patient acknowledgement form

Authority required

Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial PBS-subsidised treatment with imatinib mesylate for the chronic phase of chronic myeloid leukaemia and who has demonstrated either a major cytogenetic response or less than 1% BCR-ABL level in the blood.

First continuing applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) demonstration of a response to treatment as evidenced by either:
 - (a) major cytogenetic response [see Note explaining requirements]; or
 - (b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements].

Second and subsequent authority applications for continuing therapy with imatinib mesylate may be made on the telephone by contacting Medicare Australia on 1800 700 720 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy

Note

Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe imatinib mesylate should be forwarded to:

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

For the following diseases, written authority is required at initiation and for continuation:

Dermatofibrosarcoma protuberans;

Hypereosinophilic syndrome;

Chronic eosinophilic leukaemia;

Myelodysplastic or myeloproliferative disorder;

Aggressive systemic mastocytosis with eosinophilia.

Note

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesylate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial treatment - imatinib mesylate, dasatinib and nilotinib

From 1 April 2012, under the PBS, a patient will be able to be prescribed any of imatinib mesylate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure of response.

2. Continuing treatment with imatinib mesylate - first-line

First continuing applications are to be written and must include a pathology report demonstrating the patient has responded to the initial course of treatment.

Second and subsequent authority applications for continuing therapy with imatinib mesylate may be made on the telephone by contacting Medicare Australia on 1800 700 720 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.

3. Continuing treatment with dasatinib or nilotinib - first-line

All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows:

(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and

(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

4. For imatinib mesylate, dasatinib and nilotinib

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of second-line agents.

Where a patient has previously received PBS-subsidised treatment with imatinib mesylate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

5. Authority approval requirements.

Response criteria to initial treatment with imatinib mesylate, dasatinib or nilotinib:

For the purposes of assessing response to PBS-subsidised treatment with imatinib mesylate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with imatinib mesylate, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

6. Definitions of response.

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.

A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

7. Definitions of loss of response.

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy.							
	Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.							
9113P	imatinib 100 mg tablet, 60	1	5	..	1963.21	37.70	Glivec	NV
9114Q	imatinib 400 mg tablet, 30	1	5	..	3779.71	37.70	Glivec	NV

IMATINIB

Authority required

Treatment of patients in the accelerated phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase, and who have a primary diagnosis of chronic myeloid leukaemia. Progress to the accelerated phase is defined by the presence of 1 or more of the following:

- (1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or
- (2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%; or
- (3) Peripheral basophils greater than or equal to 20%; or
- (4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or
- (5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

Applications for authorisation must be in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in the Treatment of Chronic Myeloid Leukaemia - Supporting Information form, stating which of the above criteria are satisfied by the patient; and
- (c) a copy of the confirming pathology report from an Approved Pathology Authority in the case of criteria (1), (2), (3) and (5) above, or details of the dates of assessments in the case of progressive splenomegaly

Authority required

Treatment of patients in the blast phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase, and who have a primary diagnosis of chronic myeloid leukaemia. Progress to myeloid blast crisis is defined as either:

- (1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or
- (2) Extramedullary involvement other than spleen and liver.

Applications for authorisation must be in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in the Treatment of Chronic Myeloid Leukaemia - Supporting Information form, stating which of the above criteria are satisfied by the patient; and
- (c) a copy of the confirming pathology report from an Approved Pathology Authority in the case of criterion (1) above, or details of the date of assessment in the case of extramedullary involvement

Authority required

Continuing treatment of patients with chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase, where the patient has previously received PBS-subsidised treatment with imatinib mesylate of the accelerated phase of chronic myeloid leukaemia

Authority required

Continuing treatment of patients with chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase, where the patient has previously received PBS-subsidised treatment with imatinib mesylate of the blast phase of chronic myeloid leukaemia

Note

Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe imatinib mesylate should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

For the following diseases, written authority is required at initiation and for continuation:

Dermatofibrosarcoma protuberans;

Hypereosinophilic syndrome;

Chronic eosinophilic leukaemia;

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Myelodysplastic or myeloproliferative disorder; Aggressive systemic mastocytosis with eosinophilia.							
	Note No applications for increased repeats will be authorised.							
9115R	imatinib 100 mg tablet, 60	1	2	..	1963.21	37.70	Glivec	NV
9116T	imatinib 400 mg tablet, 30	1	2	..	3779.71	37.70	Glivec	NV

IMATINIB

Authority required

Initial treatment in combination with chemotherapy as induction or consolidation of a newly diagnosed patient with acute lymphoblastic leukaemia (ALL) bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL.

The first authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Acute Lymphoblastic Leukaemia Imatinib PBS Authority Application - Supporting Information Form; and
- (c) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided); and
- (d) a signed patient acknowledgement

Authority required

Initial treatment of a patient with acute lymphoblastic leukaemia bearing the Philadelphia chromosome or expressing the transcript BCR-ABL who has been previously treated with imatinib mesylate under the Imatinib Compassionate Program and who meets all the PBS criteria.

The first authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Acute Lymphoblastic Leukaemia Imatinib PBS Authority Application - Supporting Information Form; and
- (c) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided); and
- (d) a signed patient acknowledgement

Authority required

Continuing treatment in combination with chemotherapy as maintenance of first complete remission of patients with acute lymphoblastic leukaemia bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL.

Authority applications for continuing treatment may be made by telephone to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Imatinib mesylate is available with a lifetime maximum of 24 months for continuing treatment with imatinib mesylate therapy for patients with acute lymphoblastic leukaemia reimbursed through the PBS.

Any queries concerning the arrangements to prescribe imatinib mesylate beyond 24 months may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

Note

Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe imatinib mesylate should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

For the following diseases, written authority is required at initiation and for continuation:

Dermatofibrosarcoma protuberans;

Hypereosinophilic syndrome;

Chronic eosinophilic leukaemia;

Myelodysplastic or myeloproliferative disorder;

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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	Aggressive systemic mastocytosis with eosinophilia.							
	Note							
	Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.							
	Note							
	No applications for increased repeats will be authorised.							
9123E	imatinib 100 mg tablet, 60	1	2	..	1963.21	37.70	Glivec	NV
9124F	imatinib 400 mg tablet, 30	1	2	..	3779.71	37.70	Glivec	NV
IMATINIB								
	Authority required							
	Initial PBS-subsidised treatment of a patient with unresectable, locally recurrent or metastatic dermatofibrosarcoma protuberans.							
	Maximum dose: 800 mg per day.							
	(1) Where the application for authority to prescribe is being sought on the basis of unresectable tumour, written evidence in support of that claim must be provided; and							
	(2) Where the application for authority to prescribe is being sought on the basis of locally recurrent disease, the site of the local recurrence must be specified; and							
	(3) Where the application for authority to prescribe is being sought on the basis of metastatic disease, the site(s) of metastatic disease must be provided.							
	Applications for authorisation for initial treatment must be made in writing and must include:							
	(a) a completed authority prescription form; and							
	(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and							
	(c) a signed patient acknowledgement							
	Authority required							
	Continuing PBS-subsidised treatment of a patient with unresectable, locally recurrent or metastatic dermatofibrosarcoma protuberans who has previously been issued with an authority prescription for imatinib and who has demonstrated a response, but whose disease remains unresectable.							
	Maximum dose: 800 mg per day.							
	Applications for authorisation must be made in writing and must include:							
	(a) a completed authority prescription form; and							
	(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and							
	(c) a statement that the disease has not progressed on imatinib therapy							
	Note							
	Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).							
	Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au .							
	Written applications for authority to prescribe imatinib mesylate should be forwarded to:							
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	Prior Written Approval of Specialised Drugs							
	Reply Paid 9826							
	GPO Box 9826							
	HOBART TAS 7001							
	For the following diseases, written authority is required at initiation and for continuation:							
	Dermatofibrosarcoma protuberans;							
	Hypereosinophilic syndrome;							
	Chronic eosinophilic leukaemia;							
	Myelodysplastic or myeloproliferative disorder;							
	Aggressive systemic mastocytosis with eosinophilia.							
	Note							
	No applications for increased repeats will be authorised.							
9172R	imatinib 100 mg tablet, 60	1	2	..	1963.21	37.70	Glivec	NV
9173T	imatinib 400 mg tablet, 30	1	2	..	3779.71	37.70	Glivec	NV

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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IMATINIB								
Authority required								
Initial PBS-subsidised treatment of a patient with hypereosinophilic syndrome or chronic eosinophilic leukaemia requiring treatment and confirmed to carry the FIP1L1-PDGFR fusion gene.								
Maximum dose: 400 mg per day.								
Applications for authorisation for initial treatment must be made in writing and must include:								
(a) a completed authority prescription form; and								
(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and								
(c) a copy of the pathology report confirming the presence of the FIP1L1-PDGFR fusion gene; and								
(d) a copy of the full blood examination report confirming the presence of hypereosinophilic syndrome or chronic eosinophilic leukaemia; and								
(e) details of organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate; and								
(f) a signed patient acknowledgement								
Authority required								
Continuing PBS-subsidised treatment of a patient with hypereosinophilic syndrome or chronic eosinophilic leukaemia who has previously been issued with an authority prescription for imatinib and who has achieved and maintained a complete haematological response.								
Maximum dose: 400 mg per day.								
Applications for authorisation must be made in writing and must include:								
(a) a completed authority prescription form; and								
(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and								
(c) a copy of the full blood examination report which demonstrates a complete haematological response, with a normal eosinophil count; and								
(d) a statement that the disease has not progressed on imatinib therapy								
Note								
Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).								
Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au .								
Written applications for authority to prescribe imatinib mesylate should be forwarded to:								
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For the following diseases, written authority is required at initiation and for continuation:								
Dermatofibrosarcoma protuberans;								
Hypereosinophilic syndrome;								
Chronic eosinophilic leukaemia;								
Myelodysplastic or myeloproliferative disorder;								
Aggressive systemic mastocytosis with eosinophilia.								
Note								
No applications for increased repeats will be authorised.								
9174W	imatinib 100 mg tablet, 60	1	2	..	1963.21	37.70	Glivec	NV
9175X	imatinib 400 mg tablet, 30	1	2	..	3779.71	37.70	Glivec	NV

IMATINIB

Authority required

Initial PBS-subsidised treatment of a patient with a myelodysplastic or myeloproliferative disorder where:

(1) there is confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement either by standard karyotyping, or FISH or PDGFRB fusion gene transcript; and

(2) the patient has previously failed an adequate trial of one or more of the following conventional therapies:

— cytarabine;

— etoposide;

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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	— hydroxyurea. Maximum dose: 400 mg per day. Applications for authorisation for initial treatment must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and (c) a copy of the pathology report confirming the platelet-derived growth factor receptor (PDGFR) gene re-arrangement; and (d) a copy of the bone marrow biopsy report which demonstrates the presence of a myelodysplastic or myeloproliferative disorder; and (e) details of the prior therapy trialled and the response; and (f) a signed patient acknowledgement Authority required Continuing PBS-subsidised treatment of a patient with a PDGFRB fusion gene-positive myelodysplastic or myeloproliferative disorder who has previously been issued with an authority prescription for imatinib and who has demonstrated a complete haematological response. Maximum dose: 400 mg per day. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and (c) a copy of the full blood examination report which demonstrates a complete haematological response; and (d) a statement that the disease has not progressed on imatinib therapy Note Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au. Written applications for authority to prescribe imatinib mesylate should be forwarded to: Medicare Australia Prior Written Approval of Specialised Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 For the following diseases, written authority is required at initiation and for continuation: Dermatofibrosarcoma protuberans; Hypereosinophilic syndrome; Chronic eosinophilic leukaemia; Myelodysplastic or myeloproliferative disorder; Aggressive systemic mastocytosis with eosinophilia. Note No applications for increased repeats will be authorised.							
9176Y	imatinib 100 mg tablet, 60	1	2	..	1963.21	37.70	Glivec	NV
9177B	imatinib 400 mg tablet, 30	1	2	..	3779.71	37.70	Glivec	NV

IMATINIB

Authority required

Initial PBS-subsidised treatment of a patient with aggressive systemic mastocytosis with eosinophilia where:

- (1) there is confirmed evidence of the FIP1L1-PDGFR fusion gene; and
- (2) the patient has previously failed an adequate trial of one or more of the following conventional therapies:

— corticosteroids;

— hydroxyurea.

Maximum dose: 400 mg per day.

Applications for authorisation for initial treatment must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
- (c) a copy of the pathology report confirming the presence of the FIP1L1-PDGFR fusion gene; and

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	(d) a copy of the bone marrow biopsy report and/or other tissue biopsy report confirming the diagnosis of aggressive systemic mastocytosis and a copy of the full blood examination report demonstrating eosinophilia; and (e) details of symptomatic organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate; and (f) details of prior treatment trialled and the response; and (g) a signed patient acknowledgement Authority required Continuing PBS-subsidised treatment of a patient with aggressive systemic mastocytosis confirmed to carry the FIP1L1-PDGFRα fusion gene, who has previously been issued with an authority prescription for imatinib and who has demonstrated a complete haematological response. Maximum dose: 400 mg per day. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and (c) a copy of the full blood examination report which demonstrates a complete haematological response; and (d) a statement that the disease has not progressed on imatinib therapy Note Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au. Written applications for authority to prescribe imatinib mesylate should be forwarded to: Medicare Australia Prior Written Approval of Specialised Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 For the following diseases, written authority is required at initiation and for continuation: Dermatofibrosarcoma protuberans; Hypereosinophilic syndrome; Chronic eosinophilic leukaemia; Myelodysplastic or myeloproliferative disorder; Aggressive systemic mastocytosis with eosinophilia. Note No applications for increased repeats will be authorised.							
9178C	imatinib 100 mg tablet, 60	1	2	..	1963.21	37.70	Glivec	NV
9179D	imatinib 400 mg tablet, 30	1	2	..	3779.71	37.70	Glivec	NV

LAPATINIB

Authority required

Initial treatment, in combination with capecitabine, of a patient with HER2 positive metastatic breast cancer (equivalent to Stage IIIC or Stage IV) who has received prior therapy with a taxane, for at least 3 cycles, and whose disease has progressed despite treatment with trastuzumab for metastatic disease.

Authority applications for initial treatment must be made in writing and must include:

- (a) a completed authority prescription form;
- (b) a pathology report demonstrating HER2 positivity has been demonstrated by in situ hybridisation (ISH);
- (c) date of last treatment with a taxane and total number of cycles;
- (d) a signed patient acknowledgment;
- (e) dates of treatment with trastuzumab; and
- (f) date of demonstration of progression whilst on treatment with trastuzumab

Authority required

Continuing treatment, in combination with capecitabine, of a patient with HER2 positive metastatic breast cancer who has previously received treatment with PBS-subsidised lapatinib and who does not have progressive disease.

Authority applications must be made in writing and must include:

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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	(a) a completed authority prescription form; and (b) a statement from the prescribing doctor that the disease has not progressed Note Any queries concerning the arrangements to prescribe lapatinib may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Lapatinib should not be used in patients with a left ventricular ejection fraction (LVEF) of less than 45% or with symptomatic heart failure. Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, prior to seeking the initial authority approval and then at 3 monthly intervals during treatment. Lapatinib is not PBS-subsidised when used in combination with Commonwealth-subsidised trastuzumab. If disease progression occurs, the prescribing doctor must contact Medicare Australia within one week on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and lapatinib treatment must be ceased immediately. Note Treatment with trastuzumab for metastatic disease is defined as trastuzumab administered alone or in combination with chemotherapy for at least 6 weeks at standard doses. If treatment with a taxane is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities, including severity, can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. Note No applications for increased maximum quantities and/or repeats will be authorised.						
9148L	lapatinib 250 mg tablet, 70	2	2	..	*3387.80	37.70	Tykerb GK

NILOTINIB

Authority required

Initial treatment, as the sole PBS-subsidised therapy, of a patient in the chronic phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, BCR-ABL tyrosine kinase, and who has a primary diagnosis of chronic myeloid leukaemia.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.

Patients should be commenced on a dose of nilotinib of 300 mg twice daily. Continuing therapy is dependent on patients demonstrating a response to nilotinib therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Chronic Myeloid Leukaemia - Chronic Phase, First Line - Supporting Information form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
- (3) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow; and
- (4) a signed patient acknowledgement form

Authority required

Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial PBS-subsidised treatment with nilotinib for the chronic phase of chronic myeloid leukaemia and who has demonstrated either a major cytogenetic response or less than 1% BCR-ABL level in the blood.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) demonstration of continued response to treatment as evidenced by either:
 - (a) major cytogenetic response [see Note explaining requirements]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided; or
 - (b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided

Note

Any queries concerning the arrangements to prescribe nilotinib may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Applications for authority to prescribe nilotinib should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	Reply Paid 9826 GPO Box 9826 HOBART TAS 7001						
	Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesylate, dasatinib or nilotinib. Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent. 1. Initial treatment - imatinib mesylate, dasatinib and nilotinib From 1 April 2012, under the PBS, a patient will be able to be prescribed any of imatinib mesylate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs. During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure of response. 2. Continuing treatment with imatinib mesylate - first-line First continuing applications are to be written and must include a pathology report demonstrating the patient has responded to the initial course of treatment. Second and subsequent authority applications for continuing therapy with imatinib mesylate may be made on the telephone by contacting Medicare Australia on 1800 700 720 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy. 3. Continuing treatment with dasatinib or nilotinib - first-line All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows: (i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and (ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained. 4. For imatinib mesylate, dasatinib and nilotinib During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of second-line agents. Where a patient has previously received PBS-subsidised treatment with imatinib mesylate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent. 5. Authority approval requirements. Response criteria to initial treatment with imatinib mesylate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesylate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with imatinib mesylate, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent). 6. Definitions of response. A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response. 7. Definitions of loss of response. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.						
1309X	NILOTINIB Capsule 150 mg (as hydrochloride monohydrate), 120	1	5	..	4468.21	37.70	Tasigna NV

NILOTINIB

Authority required

Initial treatment, as the sole PBS-subsidised therapy, of a patient with chronic myeloid leukaemia in chronic or accelerated phase who has failed an adequate trial of imatinib or dasatinib as first-line treatment.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	Failure of an adequate trial of imatinib or dasatinib is defined as:						
	(i) Lack of response to initial imatinib or dasatinib therapy, defined as either: — failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or dasatinib for patients initially treated in chronic phase; or — failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or dasatinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or — failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or dasatinib; OR						
	(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or dasatinib therapy; OR						
	(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or dasatinib therapy; OR						
	(iv) Development of accelerated phase in a patient previously prescribed imatinib or dasatinib for the chronic phase of chronic myeloid leukaemia. Accelerated phase is defined by the presence of 1 or more of the following:						
	(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or						
	(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or						
	(3) Peripheral basophils greater than or equal to 20%; or						
	(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or						
	(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR						
	(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib or dasatinib therapy in patients with accelerated phase chronic myeloid leukaemia, provided that blast crisis has been excluded on bone marrow biopsy.						
	Patients should be commenced on a dose of nilotinib of 400 mg twice daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to nilotinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals.						
	Applications for authorisation must be in writing and must include:						
	(a) a completed authority prescription form; and						
	(b) a completed Chronic Myeloid Leukaemia - Second and Third Line - Supporting Information Form; and						
	(c) a signed patient acknowledgement; and						
	(d) a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale. (The date of the relevant pathology report needs to be provided); and						
	(e) where there has been a loss of response to imatinib or dasatinib, a copy of the current confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement						
	Authority required						
	Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial PBS-subsidised treatment with nilotinib for chronic myeloid leukaemia, and who has demonstrated either a major cytogenetic response, or less than 1% BCR-ABL level in the blood, to dasatinib in the preceding 18 months and thereafter at 12 monthly intervals.						
	Applications for authorisation must be in writing and must include:						
	(1) a completed authority prescription form; and						
	(2) a completed Chronic Myeloid Leukaemia - Second and Third Line - Application Form for continuing treatment; and						
	(3) demonstration of continued response to treatment as evidenced by either:						
	(a) major cytogenetic response [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided; or						
	(b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided						
	Note						
	Any queries concerning the arrangements to prescribe nilotinib may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).						
	Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.						
	Applications for authority to prescribe nilotinib should be forwarded to:						
	Medicare Australia						
	Prior Written Approval of Specialised Drugs						
	Reply Paid 9826						

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

GPO Box 9826

HOBART TAS 7001

Note

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib. Imatinib mesylate is not approved for use in second or third line treatment.

Patients are eligible for PBS-subsidised treatment with only one of dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent.

Nilotinib is not approved for patients in blast crisis.

1. Initial second line treatment

From 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib within the initial 18 month treatment period as second-line therapy, as long as only one agent is approved at a time and providing the patient did not fail that drug as first-line therapy.

During the initial 18 month treatment period, switching between approved second-line agents may only occur for reasons of intolerance, not failure of response.

2. Initial third line treatment

Third-line treatment with a TKI can only be approved when imatinib is used for first-line treatment. Patients will only be approved for PBS-subsidised treatment with one third-line agent.

From 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib providing the patient did not fail that drug as first or second line therapy and for nilotinib the patient is not in blast crisis.

3. Continuing treatment for second and third line treatment

All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows:

(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and

(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

During second line continuing treatment beyond the initial 18 month treatment period, switching between approved second line TKI agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of a third line agent.

4. Authority approval requirements.

Response criteria to initial treatment with dasatinib or nilotinib:

For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

5. Definitions of response.

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.

A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

6. Definitions of loss of response.

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy.

Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

9171Q	NILOTINIB Capsule 200 mg (as hydrochloride monohydrate), 120	1	5	..	5872.48	37.70	Tasigna	NV

PAZOPANIB

Authority required

Advanced (unresectable and/or metastatic) soft tissue sarcoma

Treatment Phase: Continuing treatment beyond 3 months

Clinical criteria:

Patient must have previously been issued with an authority prescription for pazopanib,

AND

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), AND Patient must require dose adjustment, AND The treatment must be the sole PBS-subsidised therapy for this condition. Applications for continuing therapy may be made by telephone. Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows: Complete response (CR) is disappearance of all target lesions. Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions. Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions. Stable disease (SD) is small changes that do not meet above criteria. Note No increase in the maximum quantity or number of units may be authorised. Note No increase in the maximum number of repeats may be authorised. Note Special Pricing Arrangements apply.								
10054E	pazopanib 200 mg tablet, 30	1	5	..	1256.59	37.70	Votrient	GK
10052C	pazopanib 400 mg tablet, 30	1	5	..	2410.34	37.70	Votrient	GK

PAZOPANIB

Authority required

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

Clinical criteria:

Patient must have previously been issued with an authority prescription for pazopanib,

AND

Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST),

AND

Patient must require dose adjustment,

AND

The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

Note

Patients who have progressive disease with pazopanib are no longer eligible for PBS-subsidised pazopanib.

Note

Patients who have progressive disease on sunitinib are not eligible to receive PBS-subsidised pazopanib.

Note

Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

Note

Special Pricing Arrangements apply.

2232L	pazopanib 200 mg tablet, 30	1	5	..	1256.59	37.70	Votrient	GK
2201W	pazopanib 400 mg tablet, 30	1	5	..	2410.34	37.70	Votrient	GK

PAZOPANIB

Authority required

Advanced (unresectable and/or metastatic) soft tissue sarcoma

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Treatment Phase: Initial treatment							
	Clinical criteria:							
	Patient must have a WHO performance status of 2 or less,							
	AND							
	Patient must have received prior chemotherapy treatment including an anthracycline,							
	AND							
	Patient must not have received prior treatment with an angiogenesis inhibitor,							
	AND							
	The treatment must be the sole PBS-subsidised therapy for this condition.							
	Patient must not have any of the following conditions:							
	adipocytic soft tissue sarcoma;							
	gastrointestinal stromal tumour (GIST);							
	rhabdomyosarcoma other than alveolar or pleomorphic;							
	chondrosarcoma;							
	osteosarcoma;							
	Ewings tumour/primitive neuroectodermal tumour;							
	dermofibromatosis sarcoma protuberans;							
	inflammatory myofibroblastic sarcoma;							
	malignant mesothelioma;							
	mixed mesodermal tumour of the uterus.							
	The authority application must be made in writing.							
	Note							
	No increase in the maximum quantity or number of units may be authorised.							
	Note							
	No increase in the maximum number of repeats may be authorised.							
	Note							
	Special Pricing Arrangements apply.							
10042M	pazopanib 200 mg tablet, 90	1	2	..	3542.16	37.70	Votrient	GK
10041L	pazopanib 400 mg tablet, 60	1	2	..	4673.98	37.70	Votrient	GK

PAZOPANIB

Authority required

Advanced (unresectable and/or metastatic) soft tissue sarcoma

Treatment Phase: Continuing treatment beyond 3 months

Clinical criteria:

Patient must have previously been issued with an authority prescription for pazopanib,

AND

Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST),

AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Applications for continuing therapy may be made by telephone.

Note

Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	

Note

Special Pricing Arrangements apply.

10047T	pazopanib 200 mg tablet, 90	1	5	..	3542.16	37.70	Votrient	GK
10043N	pazopanib 400 mg tablet, 60	1	5	..	4673.98	37.70	Votrient	GK

PAZOPANIB**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

Clinical criteria:

Patient must meet the Memorial Sloan Kettering Cancer Centre (MSKCC) low to intermediate risk group criteria,

AND

Patient must have a WHO performance status of 2 or less,

AND

The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

Patients who have progressive disease on sunitinib are not eligible to receive PBS-subsidised pazopanib.

Note

Patients who have developed intolerance to sunitinib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised pazopanib.

Note

Patients who have progressive disease with pazopanib are no longer eligible for PBS-subsidised pazopanib.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

Special Pricing Arrangements apply.

2029T	pazopanib 200 mg tablet, 90	1	2	..	3542.16	37.70	Votrient	GK
2030W	pazopanib 400 mg tablet, 60	1	2	..	4673.98	37.70	Votrient	GK

PAZOPANIB**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

Clinical criteria:

Patient must have previously been issued with an authority prescription for pazopanib,

AND

Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST),

AND

The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

Note

Patients who have progressive disease with pazopanib are no longer eligible for PBS-subsidised pazopanib.

Note

Patients who have progressive disease on sunitinib are not eligible to receive PBS-subsidised pazopanib.

Note

Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

Note

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Special Pricing Arrangements apply.							
	<u>Authority required</u>							
	Stage IV clear cell variant renal cell carcinoma (RCC)							
	Treatment Phase: Initial treatment							
	Clinical criteria:							
	Patient must have been receiving treatment with pazopanib prior to 1 October 2012,							
	AND							
	The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.							
	<u>Note</u>							
	Patients who have progressive disease with pazopanib are no longer eligible for PBS-subsidised pazopanib.							
	<u>Note</u>							
	Special Pricing Arrangements apply.							
2034C	pazopanib 200 mg tablet, 90	1	5	..	3542.16	37.70	Votrient	GK
2035D	pazopanib 400 mg tablet, 60	1	5	..	4673.98	37.70	Votrient	GK

SORAFENIB

Authority required

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have progressive disease according to the Response Evaluation Criteria In Solid Tumours (RECIST) following first-line treatment with a tyrosine kinase inhibitor,

AND

Patient must have a WHO performance status of 2 or less,

AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised treatment with this drug.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

Note

Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

Special Pricing Arrangements apply.

10226F	sorafenib 200 mg tablet, 60	2	2	..	*6457.42	37.70	Nexavar	BN

SORAFENIB

Authority required

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug for this condition,

AND

Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST),

AND

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	The treatment must be the sole PBS-subsidised therapy for this condition. A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug. Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows: Complete response (CR) is disappearance of all target lesions. Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions. Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions. Stable disease (SD) is small changes that do not meet above criteria. Note No increase in the maximum quantity or number of units may be authorised. Note No increase in the maximum number of repeats may be authorised. Note Special Pricing Arrangements apply.						
10242C	sorafenib 200 mg tablet, 60	2	5	..	*6457.42	37.70	Nexavar BN
	SORAFENIB <u>Authority required (STREAMLINED)</u> 4230 Advanced Barcelona Clinic Liver Cancer Stage C hepatocellular carcinoma Treatment Phase: Initial Clinical criteria: The treatment must be the sole PBS-subsidised therapy for this condition, AND Patient must have a WHO performance status of 2 or less, AND Patient must have Child Pugh class A. <u>Authority required (STREAMLINED)</u> 4234 Advanced Barcelona Clinic Liver Cancer Stage C hepatocellular carcinoma Treatment Phase: Continuing Clinical criteria: The treatment must be the sole PBS-subsidised therapy for this condition, AND Patient must have previously been treated with PBS-subsidised sorafenib, AND Patient must not have progressive disease. Note Sorafenib is not PBS-subsidised for adjunctive treatment after resection, ablation or chemoembolization. Sorafenib is not PBS-subsidised for maintenance therapy after disease progression. Note No increase in the maximum quantity or number of units may be authorised. Note No increase in the maximum number of repeats may be authorised. Note Special Pricing Arrangements apply.						
9380Q	sorafenib 200 mg tablet, 60	2	2	..	*6457.42	37.70	Nexavar BN

SUNITINIB

Authority required

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

Treatment Phase: Initial treatment

Clinical criteria:

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Patient must be symptomatic (despite somatostatin analogues); OR Patient must have disease progression, AND The treatment must be as monotherapy. Disease progression must be documented in the patient's medical records. Patients who have developed progressive disease on everolimus are not eligible to receive PBS-subsidised sunitinib for this condition. Patients who have developed intolerance to everolimus of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised sunitinib.							
	Note No increase in the maximum quantity or number of units may be authorised. Note No increase in the maximum number of repeats may be authorised. Note Special Pricing Arrangements apply.							
10004M	sunitinib 12.5 mg capsule, 28	1	2	..	1834.54	37.70	Sutent	PF
2959R	sunitinib 25 mg capsule, 28	1	2	..	3522.10	37.70	Sutent	PF
2837H	sunitinib 50 mg capsule, 28	1	2	..	6897.78	37.70	Sutent	PF

SUNITINIB

Authority required

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug,

AND

Patient must not have disease progression,

AND

The treatment must be as monotherapy.

Patients who have progressive disease with this drug are no longer eligible for PBS-subsidised treatment with this drug.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

Special Pricing Arrangements apply.

10009T	sunitinib 12.5 mg capsule, 28	1	5	..	1834.54	37.70	Sutent	PF
2842N	sunitinib 25 mg capsule, 28	1	5	..	3522.10	37.70	Sutent	PF
10010W	sunitinib 50 mg capsule, 28	1	5	..	6897.78	37.70	Sutent	PF

SUNITINIB

Authority required

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

Clinical criteria:

Patient must meet the Memorial Sloan Kettering Cancer Centre (MSKCC) low to intermediate risk group criteria,

AND

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
Patient must have a WHO performance status of 2 or less, AND The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition. Patients who have developed progressive disease on pazopanib are not eligible to receive PBS-subsidised sunitinib. Note Patients who have developed intolerance to pazopanib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised sunitinib. Note Patients who have progressive disease with sunitinib are no longer eligible for PBS-subsidised sunitinib. Note No increase in the maximum quantity or number of units may be authorised. Note No increase in the maximum number of repeats may be authorised. Note Special Pricing Arrangements apply.								
9417P	sunitinib 12.5 mg capsule, 28	1	1	..	1834.54	37.70	Sutent	PF
9418Q	sunitinib 25 mg capsule, 28	1	1	..	3522.10	37.70	Sutent	PF
9419R	sunitinib 50 mg capsule, 28	1	1	..	6897.78	37.70	Sutent	PF
SUNITINIB Authority required Stage IV clear cell variant renal cell carcinoma (RCC) Treatment Phase: Continuing treatment beyond 3 months Clinical criteria: Patient must have previously been issued with an authority prescription for sunitinib, AND Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), AND The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition. Note Patients who have progressive disease with sunitinib are no longer eligible for PBS-subsidised sunitinib. Note Patients who have developed progressive disease on pazopanib are not eligible to receive PBS-subsidised sunitinib. Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows: Complete response (CR) is disappearance of all target lesions. Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions. Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions. Stable disease (SD) is small changes that do not meet above criteria. Note Special Pricing Arrangements apply.								
9420T	sunitinib 12.5 mg capsule, 28	1	3	..	1834.54	37.70	Sutent	PF
9421W	sunitinib 25 mg capsule, 28	1	3	..	3522.10	37.70	Sutent	PF
9422X	sunitinib 50 mg capsule, 28	1	3	..	6897.78	37.70	Sutent	PF

SUNITINIB

Authority required

Initial PBS-subsidised treatment as monotherapy of a patient with WHO performance status of 2 or less with a metastatic or unresectable malignant gastrointestinal stromal tumour after failure of imatinib mesylate treatment due to resistance or intolerance.

Applications for authorisation must be in writing and must include:

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	(1) a completed authority prescription form; and (2) a completed Sunitinib Malate (Sutent) PBS Authority Application for Use in the Treatment of Gastrointestinal Stromal Tumour - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and (3) a signed patient acknowledgement. Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib Authority required Continuing PBS-subsidised treatment as monotherapy of a patient with WHO performance status of 2 or less with a metastatic or unresectable malignant gastrointestinal stromal tumour who has previously been issued with an authority prescription for sunitinib and who does not have progressive disease. Applications for continuing treatment may be made by telephone (1800 700 270, hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Patients who have failed to respond or who are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib. Patients who have progressive disease on sunitinib are no longer eligible for PBS-subsidised sunitinib Note Any queries concerning the arrangements to prescribe sunitinib malate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au. Any queries concerning patients who are enrolled on the Sunitinib Compassionate Program may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written applications for authority to prescribe sunitinib malate should be forwarded to: Medicare Australia Prior Written Approval of Specialised Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 Sunitinib malate is not PBS-subsidised for the treatment of patients with resectable malignant gastrointestinal stromal tumours. Note No applications for increased maximum quantities and/or repeats will be authorised. Note Special Pricing Arrangements apply.							
9488J	sunitinib 12.5 mg capsule, 28	1	1	..	1834.54	37.70	Sutent	PF
9489K	sunitinib 25 mg capsule, 28	1	1	..	3522.10	37.70	Sutent	PF
9490L	sunitinib 50 mg capsule, 28	1	1	..	6897.78	37.70	Sutent	PF
Other antineoplastic agents								
HYDROXYUREA								
3093T	hydroxyurea 500 mg capsule, 100	1	..	..	76.80	37.70	Hydrea	BO

ENDOCRINE THERAPY

HORMONES AND RELATED AGENTS

Progestogens

MEDROXYPROGESTERONE

Restricted benefit

Hormone-dependent breast cancer

Restricted benefit

Endometrial cancer

2725K	medroxyprogesterone acetate 100 mg tablet, 100	1	2	..	103.15	37.70	Provera	PF
2316X	medroxyprogesterone acetate 200 mg tablet, 60	1	2	..	116.42	37.70	Provera	PF
2727M	medroxyprogesterone acetate 250 mg tablet, 60	1	2	..	144.38	37.70	Provera	PF

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	MEDROXYPROGESTERONE							
	<u>Restricted benefit</u>							
	Hormone-dependent advanced breast cancer							
2728N	medroxyprogesterone acetate 500 mg tablet, 30	1	2	..	144.38	37.70	Provera	PF
	MEGESTROL							
2734X	megestrol acetate 160 mg tablet, 30	1	2	..	83.73	37.70	Megace	QA
Gonadotropin releasing hormone analogues								
	GOSERELIN							
	<u>Restricted benefit</u>							
	Carcinoma of the prostate							
	Clinical criteria:							
	The condition must be locally advanced (stage C); OR							
	The condition must be metastatic (stage D).							
8093Y	goserelin 10.8 mg implant, 1	1	1	..	1109.10	37.70	Zoladex 10.8 Implant	AP
	GOSERELIN							
	<u>Restricted benefit</u>							
	Carcinoma of the prostate							
	Clinical criteria:							
	The condition must be locally advanced (stage C); OR							
	The condition must be metastatic (stage D).							
	<u>Restricted benefit</u>							
	Breast cancer							
	Clinical criteria:							
	The condition must be locally advanced (stage III); OR							
	The condition must be metastatic (stage IV),							
	AND							
	The condition must be hormone receptor positive.							
	<u>Restricted benefit</u>							
	Endometriosis							
	Clinical criteria:							
	The condition must be visually proven,							
	AND							
	The treatment must be for the short-term (up to 6 months).							
	<u>Note</u>							
	Only 1 course of not more than 6 months' therapy will be authorised.							
	<u>Restricted benefit</u>							
	Breast cancer							
	Clinical criteria:							
	The condition must be hormone receptor positive,							
	AND							
	The treatment must be an alternative to adjuvant chemotherapy.							
1454M	goserelin 3.6 mg implant, 1	1	5	..	333.34	37.70	Zoladex Implant	AP
	GOSERELIN (&) BICALUTAMIDE							
	<u>Restricted benefit</u>							
	Carcinoma of the prostate							
	Clinical criteria:							
	The condition must be metastatic (stage D),							

Patient must require a combination of an antiandrogen and a GnRH (LH-RH) agonist.

No increase in the maximum quantity or number of units may be authorised.

No increase in the maximum number of repeats may be authorised.

9065D	goserelin 10.8 mg implant [1 implant] (&) bicalutamide 50 mg tablet [28 tablets], 1 pack	#1	..	..	1248.63	37.70	ZolaCos CP 10.8/50(28)	AP
9066E	goserelin 10.8 mg implant [1 implant] (&) bicalutamide 50 mg tablet [84 tablets], 1 pack	#1	1	..	1527.71	37.70	ZolaCos CP 10.8/50(84)	AP
9064C	goserelin 3.6 mg implant [1 implant] (&) bicalutamide 50 mg tablet [28 tablets], 1 pack	#1	5	..	477.71	37.70	ZolaCos CP 3.6/50	AP

3229

Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate

8708H	leuporelin acetate 22.5 mg injection: modified release [1 syringe] (&) inert substance diluent [1 syringe], 1 pack	1	1	..	1109.10	37.70	Eligard 3 month	TL
8876E	leuporelin acetate 22.5 mg injection: modified release [1 x 22.5 mg syringe] (&) inert substance diluent [1 x 2 mL syringe], 1 pack	1	1	..	1109.10	37.70	Lucrin Depot 3 Month PDS	VE
8709J	leuporelin acetate 30 mg injection: modified release [1 syringe] (&) inert substance diluent [1 syringe], 1 pack	1	1	..	1451.67	37.70	Eligard 4 month	TL
8877F	leuporelin acetate 30 mg injection: modified release [1 x 30 mg syringe] (&) inert substance diluent [1 x 2 mL syringe], 1 pack	1	1	..	1451.67	37.70	Lucrin Depot 4 Month PDS	VE
8859G	leuporelin acetate 45 mg injection: modified release [1 syringe] (&) inert substance diluent [1 syringe], 1 pack	1	..	..	2124.32	37.70	Eligard 6 month	TL
8707G	leuporelin acetate 7.5 mg injection: modified release [1 syringe] (&) inert substance diluent [1 syringe], 1 pack	1	5	..	420.54	37.70	Eligard 1 month	TL
8875D	leuporelin acetate 7.5 mg injection: modified release [1 x 7.5 mg syringe] (&) inert substance diluent [1 x 2 mL syringe], 1 pack	1	5	..	420.54	37.70	Lucrin Depot 7.5mg PDS	VE

4871

Central precocious puberty

Treatment Phase: Continuing treatment

Patient must have previously been issued with an authority prescription for this drug for this condition.

Must be treated by a medical practitioner in consultation with a paediatric endocrinologist; OR

Must be treated by a medical practitioner in consultation with an endocrinologist specialising in paediatrics.

10255R	leuporelin acetate 30 mg injection: modified release [1 syringe] (&) inert substance diluent [1 syringe], 1 pack	#1	1	..	1451.67	37.70	Lucrin Depot Paediatric 30 mg PDS	VE

Central precocious puberty

Treatment Phase: Initial treatment

Population criteria:

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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	Patient must be under 8 years of age (girls) or 9 years of age (boys); OR Patient must have received treatment with a gonadotropin releasing hormone analogue (GnRHa) for this condition prior to 1 May 2015. Treatment criteria: Must be treated by a paediatric endocrinologist; OR Must be treated by an endocrinologist specialising in paediatrics.							
10256T	leuporelin acetate 30 mg injection: modified release [1 syringe] (&) inert substance diluent [1 syringe], 1 pack	1	1	..	1451.67	37.70	Lucrin Depot Paediatric 30 mg PDS	VE
	TRIPTORELIN Authority required (STREAMLINED) 3229 Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate							
9379P	triptorelin 11.25 mg injection [1 x 11.25 mg vial] (&) inert substance diluent [1 x 2 mL ampoule], 1 pack	1	1	..	1109.10	37.70	Diphereline	IS
5297T	triptorelin 22.5 mg injection [1 x 22.5 mg vial] (&) inert substance diluent [1 x 2 mL ampoule], 1 pack	1	..	..	2124.32	37.70	Diphereline	IS
9378N	triptorelin 3.75 mg injection [1 x 3.75 mg vial] (&) inert substance diluent [1 x 2 mL ampoule], 1 pack	1	5	..	420.54	37.70	Diphereline	IS
HORMONE ANTAGONISTS AND RELATED AGENTS Anti-estrogens								
	TAMOXIFEN Restricted benefit Treatment of hormone-dependent breast cancer							
	Note This drug is not PBS-subsidised for primary prevention of breast cancer.							
	Note Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
2109B NP	tamoxifen 10 mg tablet, 60	1	5	..	21.78	22.93	Genox 10	AF
	TAMOXIFEN Restricted benefit Treatment of hormone-dependent breast cancer							
	Note This drug is not PBS-subsidised for primary prevention of breast cancer.							
	Note For item codes 2110C and 1880Y, pharmaceutical benefits that have the form tablet 20 mg (base) are equivalent for the purposes of substitution.							
	Note Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
1880Y NP	tamoxifen 20 mg tablet, 30	2	5	^B 1.88	*34.68	33.95	^a Nolvadex-D	AP
2110C NP	tamoxifen 20 mg tablet, 60	1	5	..	32.80	33.95	^a Genox 20	AF
							^a GenRx Tamoxifen	GX
							^a Tamosin	QA
							^a Tamoxen 20 mg	GN
							^a Tamoxifen Sandoz	SZ
	TOREMIFENE							
8216K	toremifene 60 mg tablet, 30	1	5	..	74.08	37.70	Fareston	MK

Anti-androgens

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
BICALUTAMIDE							
<u>Authority required (STREAMLINED)</u>							
3674							
Metastatic (equivalent to stage D) prostatic carcinoma in combination with GnRH (LH-RH) analogue therapy							
<u>Note</u>							
No applications for increased maximum quantities and/or repeats will be authorised.							
<u>Note</u>							
Shared Care Model:							
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
8094B NP	bicalutamide 50 mg tablet, 28	1	5	..	103.54	37.70	a APO-Bicalutamide TX
							a Bicalox ER
							a Bicalutamide AN EA
							a Bicalutamide-GA GN
							a Calutex QA
							a Cosamide AF
							a Cosudex AP
CYPROTERONE							
<u>Authority required (STREAMLINED)</u>							
1014							
Advanced carcinoma of the prostate							
<u>Authority required (STREAMLINED)</u>							
1404							
To reduce drive in sexual deviations in males							
8019C	cyproterone acetate 100 mg tablet, 50	1	5	..	85.11	37.70	a Cyprocur 100 QA
							a Cyprostat-100 SY
							a Cyproterone AN EA
							a Cyproterone Sandoz HX
							a GenRx Cyproterone Acetate GX
							a Procur 100 GN
				^B 0.80	85.91	37.70	a Androcure-100 BN
1270W	cyproterone acetate 50 mg tablet, 50	2	5	..	*107.36	37.70	a Cyprocur 50 QA
							a Cyprone AF
							a Cyprostat SY
							a Cyproterone AN EA
							a Cyproterone Sandoz HX
							a Cyrotone ER
							a GenRx Cyproterone Acetate GX
							a Procur GN
				^B 1.88	*109.24	37.70	a Androcure BN

ENZALUTAMIDE

Authority required

Castration resistant metastatic carcinoma of the prostate

Clinical criteria:

The treatment must not be used in combination with chemotherapy,

AND

Patient must have failed treatment with docetaxel due to resistance or intolerance; OR

Patient must be unsuitable for docetaxel treatment on the basis of predicted intolerance to docetaxel,

AND

Patient must have a WHO performance status of 2 or less,

AND

Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug,

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
AND								
Patient must not have received prior treatment with abiraterone; OR								
Patient must have developed intolerance to abiraterone of a severity necessitating permanent treatment withdrawal.								
Note								
Special Pricing Arrangements apply.								
Note								
No increase in the maximum quantity or number of units may be authorised.								
Note								
No increase in the maximum number of repeats may be authorised.								
10174L	enzalutamide 40 mg capsule, 112	1	2	..	3700.00	37.70	Xtandi	LL
FLUTAMIDE								
Authority required (STREAMLINED)								
3674								
Metastatic (equivalent to stage D) prostatic carcinoma in combination with GnRH (LH-RH) analogue therapy								
Note								
No applications for increased maximum quantities and/or repeats will be authorised.								
Note								
Shared Care Model:								
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
1417N NP	flutamide 250 mg tablet, 100	1	5	..	181.97	37.70	Flutamin	AF
NILUTAMIDE								
Authority required (STREAMLINED)								
3675								
Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) prostatic carcinoma, in combination with GnRH (LH-RH) analogue therapy								
Authority required (STREAMLINED)								
3300								
Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) prostatic carcinoma, in conjunction with surgical orchidectomy								
Note								
Shared Care Model:								
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8131Y NP	nilutamide 150 mg tablet, 30	1	5	..	236.90	37.70	Anandron	SW
Aromatase inhibitors								
ANASTROZOLE								
Restricted benefit								
Breast cancer								
Clinical criteria:								
The condition must be hormone receptor positive.								
Population criteria:								
Patient must not be pre-menopausal.								
Note								
This drug is not PBS-subsidised for primary prevention of breast cancer.								
Note								
This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer where the total duration of this drug (or any other aromatase inhibitor) treatment extends beyond 5 years.								
Note								
Shared Care Model:								
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8179L NP	anastrozole 1 mg tablet, 30	1	5	..	85.59	37.70 ^a	Anastrol	QA

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							a Anastrozole AN	EA
							a Anastrozole-DRLA	RZ
							a Anastrozole FBM	FO
							a Anastrozole-GA	GN
							a Anastrozole GH	GQ
							a Anastrozole RBX	RA
							a Anastrozole Sandoz	SZ
							a Anzole	UA
							a APO-Anastrozole	TX
							a Arianna	AF
							a Arimidex	AP
							a Azastrole	ER
							a Chem mart Anastrozole	CH
							a Pharmacor Anastrozole 1	CR
							a Pharmacy Choice Anastrozole	RI
							a Terry White Chemists Anastrozole	TW

EXEMESTANE

Restricted benefit

Metastatic (Stage IV) breast cancer

Clinical criteria:

The condition must be hormone receptor positive,

AND

The condition must be human epidermal growth factor receptor 2 (HER2) negative,

AND

Patient must be receiving PBS-subsidised everolimus concomitantly for this condition.

Population criteria:

Patient must not be pre-menopausal.

10103R	exemestane 25 mg tablet, 30	1	5	..	106.86	37.70	a APO-Exemestane	TX
							a Aromasin	PF
							a Exaccord	RA
							a Exemestane AN	EA
							a Exemestane-GA	GN
							a Exemestane GH	GQ
							a Exemestane Pfizer	FZ
							a Exemestane Sandoz	SZ

EXEMESTANE

Restricted benefit

Advanced breast cancer

Clinical criteria:

The condition must be hormone receptor positive,

AND

The condition must have progressed following treatment with tamoxifen.

Population criteria:

Patient must not be pre-menopausal.

Restricted benefit

Early breast cancer

Clinical criteria:

The condition must be hormone receptor positive,

AND

The condition must have previously been treated with tamoxifen for a minimum of 2 years.

Population criteria:

Patient must not be pre-menopausal.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
Note This drug is not PBS-subsidised for primary prevention of breast cancer. Note This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer extended beyond 5 years, i.e. a patient who has received 2 years of tamoxifen therapy may only receive 3 years of PBS-subsidised treatment with exemestane. Note Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
8506Q NP	exemestane 25 mg tablet, 30	1	5	..	106.86	37.70	^a APO-Exemestane TX ^a Aromasin PF ^a Exaccord RA ^a Exemestane AN EA ^a Exemestane-GA GN ^a Exemestane GH GQ ^a Exemestane Pfizer FZ ^a Exemestane Sandoz SZ
LETROZOLE Restricted benefit Breast cancer Clinical criteria: The condition must be hormone receptor positive. Population criteria: Patient must not be pre-menopausal. Restricted benefit Early breast cancer Clinical criteria: The condition must be hormone receptor positive, AND The treatment must be for extended adjuvant treatment of the condition commencing within 6 months of ceasing treatment with tamoxifen. Population criteria: Patient must not be pre-menopausal. Note This drug is not PBS-subsidised for primary prevention of breast cancer. Note This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer where the total duration of this drug (or any other aromatase inhibitor) treatment extends beyond 5 years. Note Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
8245Y NP	letrozole 2.5 mg tablet, 30	1	5	..	80.43	37.70	^a APO-Letrozole TX ^a Chem mart Letrozole CH ^a Femara 2.5 mg NV ^a Femolet AF ^a Fera QA ^a Gynotril ER ^a Letrozole Actavis VN ^a Letrozole AN EA ^a Letrozole-DRLA RZ ^a Letrozole FBM FO ^a Letrozole-GA GN ^a Letrozole generichealth GQ ^a Letrozole RBX RA ^a Letrozole Sandoz SZ ^a Lezole UA

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							^a Pharmacor Letrozole 2.5	CR
							^a Pharmacy Choice Letrozole	RI
							^a Terry White Chemists Letrozole	TW

Other hormone antagonists and related agents

ABIRATERONE

Authority required

Castration resistant metastatic carcinoma of the prostate

Clinical criteria:

The treatment must be in combination with prednisone or prednisolone,

AND

The treatment must not be used in combination with chemotherapy,

AND

Patient must have failed treatment with docetaxel due to resistance or intolerance; OR

Patient must be unsuitable for docetaxel treatment on the basis of predicted intolerance to docetaxel,

AND

Patient must have a WHO performance status of 2 or less,

AND

Patient must not receive PBS-subsidised abiraterone if progressive disease develops while on abiraterone,

AND

Patient must not have received prior treatment with enzalutamide; OR

Patient must have developed intolerance to enzalutamide of a severity necessitating permanent treatment withdrawal.

Note

Special Pricing Arrangements apply.

2698B	abiraterone acetate 250 mg tablet, 120	1	2	..	3600.24	37.70	Zytiga	JC

DEGARELIX

Authority required (STREAMLINED)

3229

Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate

Note

No applications for increased maximum quantities and/or repeats will be authorised for the 120 mg powder for injection.

2785N	degarelix 120 mg injection [2 x 120 mg vials] (&) inert substance diluent [2 syringes], 1 pack	1	..	..	439.06	37.70	Firmagon 120mg	FP

DEGARELIX

Authority required (STREAMLINED)

3229

Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate

2784M	degarelix 80 mg injection [1 x 80 mg vial] (&) inert substance diluent [1 syringe], 1 pack	1	5	..	420.54	37.70	Firmagon 80mg	FP

IMMUNOSTIMULANTS

IMMUNOSTIMULANTS

Interferons

INTERFERON ALFA-2A

Authority required

Hairy cell leukaemia

Authority required

Myeloproliferative disease with excessive thrombocytosis

Caution

Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.								
8180M	interferon alfa-2a 3 million international units/0.5 mL injection, 1 x 0.5 mL syringe	15	4	..	*506.56	37.70	Roferon-A	RO
INTERFERON ALFA-2A								
Authority required								
Low grade non-Hodgkin's lymphoma with clinical features suggestive of a poor prognosis, in combination with anthracycline-based chemotherapy								
Caution								
Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.								
8181N	interferon alfa-2a 3 million international units/0.5 mL injection, 1 x 0.5 mL syringe	15	5	..	*506.56	37.70	Roferon-A	RO
8182P	interferon alfa-2a 4.5 million international units/0.5 mL injection, 1 x 0.5 mL syringe	5	5	..	*265.06	37.70	Roferon-A	RO
8183Q	interferon alfa-2a 6 million international units/0.5 mL injection, 1 x 0.5 mL syringe	5	5	..	*345.06	37.70	Roferon-A	RO
8184R	interferon alfa-2a 9 million international units/0.5 mL injection, 1 x 0.5 mL syringe	5	5	..	*506.46	37.70	Roferon-A	RO
INTERFERON ALFA-2A								
Authority required								
Myeloproliferative disease with excessive thrombocytosis								
Caution								
Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.								
8551C	interferon alfa-2a 4.5 million international units/0.5 mL injection, 1 x 0.5 mL syringe	5	4	..	*265.06	37.70	Roferon-A	RO
8552D	interferon alfa-2a 6 million international units/0.5 mL injection, 1 x 0.5 mL syringe	5	4	..	*345.06	37.70	Roferon-A	RO
8553E	interferon alfa-2a 9 million international units/0.5 mL injection, 1 x 0.5 mL syringe	5	4	..	*506.46	37.70	Roferon-A	RO
INTERFERON ALFA-2B								
Authority required								
Maintenance treatment of multiple myeloma once remission has been achieved with chemotherapy								
Authority required								
Low grade non-Hodgkin's lymphoma with clinical features suggestive of a poor prognosis, in combination with anthracycline-based chemotherapy								
Caution								
Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.								
8348J	interferon alfa-2b 18 million international units/1.2 mL injection, 1 x 1.2 mL cartridge	3	5	..	*606.37	37.70	Intron A Redipen	MK
8476D	interferon alfa-2b 30 million international units/1.2 mL injection, 1 x 1.2 mL cartridge	3	5	..	*1006.09	37.70	Intron A Redipen	MK
INTERFERON ALFA-2B								
Authority required								
Hairy cell leukaemia								
Caution								
Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.								
8572E	interferon alfa-2b 18 million international units/1.2 mL injection, 1 x 1.2 mL cartridge	3	4	..	*606.37	37.70	Intron A Redipen	MK

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
INTERFERON BETA-1A								
<u>Authority required (STREAMLINED)</u>								
4881								
Multiple sclerosis								
Treatment Phase: Initial treatment								
Clinical criteria:								
The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR								
The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient,								
AND								
Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years,								
AND								
Patient must be ambulatory (without assistance or support).								
Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.								
<u>Authority required (STREAMLINED)</u>								
4887								
Multiple sclerosis								
Treatment Phase: Continuing treatment								
Clinical criteria:								
The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis,								
AND								
Patient must have previously been issued with an authority prescription for this drug,								
AND								
Patient must not show continuing progression of disability while on treatment with this drug,								
AND								
Patient must have demonstrated compliance with, and an ability to tolerate this therapy.								
<u>Note</u>								
No increase in the maximum quantity or number of units may be authorised.								
<u>Note</u>								
No increase in the maximum number of repeats may be authorised.								
8968B	INTERFERON BETA-1a Injection 44 micrograms (12,000,000 i.u.) in 0.5 mL single dose autoinjector, 12	1	5	..	1057.11	37.70	Rebif 44	SG
8289G	interferon beta-1a 30 microgram (6 million international units) injection [4 x 30 microgram vials] (&) inert substance diluent [4 x 1.1 mL syringes], 1 pack	1	5	..	1057.11	37.70	Avonex	BD
8805K	interferon beta-1a 30 microgram/0.5 mL (6 million international units) injection, 4 x 0.5 mL syringes	1	5	..	1057.11	37.70	Avonex	BD
8403G	interferon beta-1a 44 microgram/0.5 mL (12 million international units) injection, 12 x 0.5 mL syringes	1	5	..	1057.11	37.70	Rebif 44	SG
9332E	interferon beta-1a 44 microgram/0.5 mL (12 million international units) injection, 4 x 1.5 mL cartridges	1	5	..	1057.11	37.70	Rebif 44	SG

INTERFERON BETA-1B

Authority required (STREAMLINED)

4881

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, AND Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, AND Patient must be ambulatory (without assistance or support). Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records. <u>Authority required (STREAMLINED)</u> 4887 Multiple sclerosis Treatment Phase: Continuing treatment Clinical criteria: The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, AND Patient must have previously been issued with an authority prescription for this drug, AND Patient must not show continuing progression of disability while on treatment with this drug, AND Patient must have demonstrated compliance with, and an ability to tolerate this therapy. <u>Note</u> No increase in the maximum quantity or number of units may be authorised. <u>Note</u> No increase in the maximum number of repeats may be authorised.							
8101J	interferon beta-1b 8 million international units (250 microgram) injection [15 x 250 microgram vials] (&) inert substance diluent [15 x 1.2 mL syringes], 1 pack	1	5	..	1001.15	37.70	Betaferon	BN
	PEGINTERFERON BETA-1A <u>Authority required</u> Multiple sclerosis Treatment Phase: Initial treatment Clinical criteria: The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, AND Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, AND Patient must be ambulatory (without assistance or support). Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application. <u>Note</u> No increase in the maximum quantity or number of units may be authorised. <u>Note</u> No increase in the maximum number of repeats may be authorised.							
10212L	peginterferon beta-1a 125 microgram/0.5 mL injection, 2 x 0.5 mL injection devices	1	4	..	1057.11	37.70	Plegridy	BD
10218T	peginterferon beta-1a 63 microgram/0.5 mL injection [0.5 mL injection device] (&) peginterferon beta-1a 94 microgram/0.5 mL injection [0.5 mL injection device], 1	1	..	..	1057.11	37.70	Plegridy	BD

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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	pack							
	PEGINTERFERON BETA-1A							
	<u>Authority required</u>							
	Multiple sclerosis							
	Treatment Phase: Continuing treatment							
	Clinical criteria:							
	Patient must have previously been issued with an authority prescription for this drug,							
	AND							
	Patient must not show continuing progression of disability while on treatment with this drug,							
	AND							
	Patient must have demonstrated compliance with, and an ability to tolerate this therapy.							
	<u>Note</u>							
	No increase in the maximum quantity or number of units may be authorised.							
	<u>Note</u>							
	No increase in the maximum number of repeats may be authorised.							
10220X	peginterferon beta-1a 125 microgram/0.5 mL injection, 2 x 0.5 mL injection devices	1	5	..	1057.11	37.70	Plegridy	BD

Other immunostimulants

BACILLUS CALMETTE AND GUERIN-CONNAUGHT STRAIN

Restricted benefit

Treatment of carcinoma in situ of the urinary bladder

1140B	Bacillus Calmette and Guerin-Connaught strain 660 million colony forming units injection [1 x 81 mg vial] (&) inert substance diluent [1 x 3 mL vial], 1 pack	3	1	..	*460.21	37.70	ImmuCyst	SW

BACILLUS CALMETTE AND GUERIN-TICE STRAIN

Restricted benefit

Primary and relapsing superficial urothelial carcinoma of the bladder

1131M	Bacillus Calmette and Guerin-Tice strain 500 million colony forming units injection, 3 x 500 million colony forming units vials	1	1	..	556.73	37.70	OncoTICE	MK

GLATIRAMER ACETATE

Authority required (STREAMLINED)

4881

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient,

AND

Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years,

AND

Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

Authority required (STREAMLINED)

4887

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, AND Patient must have previously been issued with an authority prescription for this drug, AND Patient must not show continuing progression of disability while on treatment with this drug, AND Patient must have demonstrated compliance with, and an ability to tolerate this therapy. Note No increase in the maximum quantity or number of units may be authorised. Note No increase in the maximum number of repeats may be authorised.							
8726G	glatiramer acetate 20 mg/mL injection, 28 x 1 mL syringes	1	5	..	1092.99	37.70	Copaxone TB

IMMUNOSUPPRESSANTS

IMMUNOSUPPRESSANTS

Selective immunosuppressants

ABATACEPT

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have severe active rheumatoid arthritis,

AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months,

AND

Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times,

AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly,

AND

Patient must not receive more than 16 weeks of treatment under this restriction,

AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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	For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab. If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. The authority application must be made in writing and must include: (1) completed authority prescription forms; and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and (3) a signed patient acknowledgement. Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats. Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats. Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased. Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.						

Note

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;

(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note

No increase in the maximum quantity or number of units may be authorised.

No increase in the maximum number of repeats may be authorised.

Special Pricing Arrangements apply.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

[illegible]

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

[illegible]

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

No increase in the maximum quantity or number of units may be authorised.

No increase in the maximum number of repeats may be authorised.

Special Pricing Arrangements apply.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

[illegible]

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. <u>Authority required</u> Severe active rheumatoid arthritis Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply. Clinical criteria: Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. Treatment criteria: Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. <u>Note</u> Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001						
1220F	abatacept 125 mg/mL injection, 4 x 1 mL syringes	1	3	..	1754.25	37.70	Orencia

BQ

ABATACEPT

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment.

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis,

AND

Patient must have demonstrated an adequate response to treatment with this drug,

AND

Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction,

AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Note No increase in the maximum quantity or number of units may be authorised. No increase in the maximum number of repeats may be authorised. Special Pricing Arrangements apply. Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 HOBART TAS 7001 Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept). Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time. In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist. A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements: - a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, - a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and - once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis. For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alpha antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.						

[illegible]

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	subcutaneous formulation. In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment. To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period. To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing. (3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. <u>Authority required</u> Severe active rheumatoid arthritis Treatment Phase: Continuing Treatment – balance of supply. Clinical criteria: Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Treatment criteria: Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. <u>Note</u> Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001						
1221G	abatacept 125 mg/mL injection, 4 x 1 mL syringes	1	5	..	1754.25	37.70	Orencia BQ

EVEROLIMUS

Authority required

Maintenance therapy, following initiation and stabilisation of treatment with everolimus and where therapy remains under the supervision and direction of the transplant unit reviewing that patient, of patients with renal transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application

Authority required

Maintenance therapy, following initiation and stabilisation of treatment with everolimus and where therapy remains under the supervision and direction of the transplant unit reviewing that patient, of patients with cardiac transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application

Caution

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Careful monitoring of patients is mandatory.							
9352F	everolimus 1 mg tablet, 60	2	3	..	*2069.10	37.70	Certican	NV
8840G	everolimus 250 microgram tablet, 60	1	3	..	283.13	37.70	Certican	NV
8841H	everolimus 500 microgram tablet, 60	1	3	..	544.17	37.70	Certican	NV
8842J	everolimus 750 microgram tablet, 60	2	3	..	*1578.96	37.70	Certican	NV

FINGOLIMOD

Authority required

Initial treatment, as monotherapy, of clinically definite relapsing-remitting multiple sclerosis in an ambulatory (without assistance or support) patient who has experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years. The diagnosis must be confirmed by magnetic resonance imaging of the brain and/or spinal cord and the date of the scan included in the authority application, unless the authority application is accompanied by written certification provided by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient. The authority will be limited to the maximum quantity and number of repeats indicated in the schedule

Authority required

Continuing treatment, as monotherapy, of clinically definite relapsing-remitting multiple sclerosis in a patient previously issued with an authority prescription for this drug who does not show continuing progression of disability while on treatment with this drug and who has demonstrated compliance with, and an ability to tolerate, this therapy. Authorities will be limited to the maximum quantity and number of repeats indicated in the schedule

Note

Special Pricing Arrangements apply.

5262Y	fingolimod 500 microgram capsule, 28	1	5	..	2313.32	37.70	Gilenya	NV

LEFLUNOMIDE

Authority required (STREAMLINED)

2682

Treatment of severe active psoriatic arthritis where other disease modifying anti-rheumatic drugs (including methotrexate) are ineffective and/or inappropriate. Treatment must be initiated by a physician

Caution

Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

5449T	leflunomide 10 mg tablet, 30	1	5	..	48.94	37.70	^a Arabloc	AV
							^a Arava	SW
							^a Leflunomide Sandoz	SZ
5450W	leflunomide 20 mg tablet, 30	1	5	..	69.85	37.70	^a Arabloc	AV
							^a Arava	SW
							^a Leflunomide Sandoz	SZ

LEFLUNOMIDE

Authority required (STREAMLINED)

2644

Treatment of severe active rheumatoid arthritis where other disease modifying anti-rheumatic drugs (including methotrexate) are ineffective and/or inappropriate. Treatment must be initiated by a physician

Caution

Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

8374R	leflunomide 10 mg tablet, 30	1	5	..	48.94	37.70	^a APO-Leflunomide	TX
							^a Arabloc	AV
							^a Arava	SW
							^a Leflunomide AN	EA
							^a Leflunomide-GA	GN
							^a Leflunomide GH	GQ
							^a Leflunomide Sandoz	SZ
							^a Lunava 10	ZP
8375T	leflunomide 20 mg tablet, 30	1	5	..	69.85	37.70	^a APO-Leflunomide	TX

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
							a Arabloc AV
							a Arava SW
							a Leflunomide AN EA
							a Leflunomide-GA GN
							a Leflunomide GH GQ
							a Leflunomide Sandoz SZ
							a Lunava 20 ZP

MYCOPHENOLATE

Caution

Careful monitoring of patients is mandatory.

2150E	mycophenolate 180 mg tablet: enteric, 120 tablets	1	5	..	135.45	37.70	Myfortic	NV
2193K	mycophenolate 360 mg tablet: enteric, 120 tablets	1	5	..	258.73	37.70	Myfortic	NV
8651H	mycophenolate mofetil 1 g/5 mL oral liquid: powder for, 165 mL	‡1	5	..	#290.29	37.70	CellCept	RO
8650G	mycophenolate mofetil 500 mg tablet, 50	3	5	..	*317.23	37.70	^a APO-Mycophenolate	TX
							^a CellCept	RO
							^a Ceptolate	AF
							^a Mycophenolate Sandoz	SZ
							^a Pharmacor	CR
							Mycophenolate 500	

MYCOPHENOLATE

Caution

Careful monitoring of patients is mandatory.

Note

For item codes 8649F and 1836P, pharmaceutical benefits that have the form capsule 250 mg are equivalent for the purposes of substitution.

1836P	mycophenolate Capsule 250 mg, 50	6	5	..	*317.26	37.70	^a	Ceptolate	AF
8649F	mycophenolate mofetil 250 mg capsule, 100	3	5	..	*317.26	37.70	^a	APO-Mycophenolate	TX
							^a	CellCept	RO
							^a	Mycophenolate Sandoz	SZ
							^a	Pharmacor	CR
								Mycophenolate 250	

SIROLIMUS

Caution

Careful monitoring of patients is mandatory.

8724E	sirolimus 1 mg tablet, 100	1	3	..	815.59	37.70	Rapamune	PF
8725F	sirolimus 1 mg/mL oral liquid, 60 mL	‡1	3	..	530.08	37.70	Rapamune	PF
8833X	sirolimus 2 mg tablet, 100	1	3	..	1584.03	37.70	Rapamune	PF
8984W	sirolimus 500 microgram tablet, 100	1	3	..	413.63	37.70	Rapamune	PF

TERIFLUNOMIDE

Authority required

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient,

AND

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	The treatment must be as monotherapy, AND Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years; OR Patient must have been receiving treatment with this drug prior to 1 December 2013, AND Patient must be ambulatory (without assistance or support). Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application. Authority required Multiple sclerosis Treatment Phase: Continuing treatment Clinical criteria: The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, AND The treatment must be as monotherapy, AND Patient must have previously been issued with an authority prescription for this drug, AND Patient must not show continuing progression of disability while on treatment with this drug. Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application. Caution Teriflunomide is a category X drug and must not be given to pregnant women or women of childbearing potential who are not currently using reliable contraception. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out. Note No increase in the maximum quantity or number of units may be authorised. Note No increase in the maximum number of repeats may be authorised. Note Special Pricing Arrangements apply.						
2898M	teriflunomide 14 mg tablet, 28	1	5	..	1847.26	37.70	Aubagio GZ

Tumor necrosis factor alpha (TNF-) inhibitors

ADALIMUMAB

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years,

AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months; OR

Patient must have received no PBS-subsidised bDMARD treatment for at least 5 years if they failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) in their last treatment cycle,

AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2

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	g daily; OR						
	Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND Patient must not receive more than 16 weeks of treatment under this restriction. Population criteria: Patient must be aged 18 years or older. Treatment criteria: Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab. If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The application must include details of the DMARDs trialed, their doses and duration of treatment, and all relevant contraindications and/or intolerances. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and (3) a signed patient acknowledgement.						

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle.

Note

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2). Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy. A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course. (b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. (2) Swapping therapy. Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing. (3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement. (4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy. A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction. <u>Authority required</u> Severe active juvenile idiopathic arthritis Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 24 months) Clinical criteria: Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, AND Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, AND Patient must not have failed PBS-subsidised therapy with adalimumab for this condition in the current treatment cycle, AND Patient must not receive more than 16 weeks of treatment under this restriction. Population criteria: Patient must be aged 18 years or older. Treatment criteria: Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.						

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has received PBS-subsidised treatment with adalimumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised adalimumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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(change or recommencement of treatment after break of less than 24 months) – balance of supply								
Clinical criteria:								
Patient must have received insufficient adalimumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR								
Patient must have received insufficient adalimumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment,								
AND								
The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.								
Treatment criteria:								
Must be treated by a rheumatologist; OR								
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.								
Note								
Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).								
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:								
Department of Human Services								
Prior Written Approval of Complex Drugs								
Reply Paid 9826								
GPO Box 9826								
HOBART TAS 7001								
5282B	adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges	1	3	..	1774.70	37.70	Humira	VE
5281Y	adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	1	3	..	1774.70	37.70	Humira	VE

ADALIMUMAB

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years,

AND

Patient must have demonstrated an adequate response to treatment with adalimumab,

AND

Patient must have received adalimumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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					Price for Max. Qty \$	Recordable Value for Safety Net \$	
	(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).						

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

- (1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

- (a) Initial treatment.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).								
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:								
Department of Human Services								
Prior Written Approval of Complex Drugs								
Reply Paid 9826								
GPO Box 9826								
HOBART TAS 7001								
5284D	adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges	1	5	..	1774.70	37.70	Humira	VE
5283C	adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	1	5	..	1774.70	37.70	Humira	VE

ADALIMUMAB

Authority required

Initial 1

Initial treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and

(b) has an externally draining enterocutaneous or rectovaginal fistula; and

(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

Authority applications must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and

(ii) a signed patient acknowledgement.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum of 16 weeks treatment will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

Authority required

Initial 2

Change or re-commencement of treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with adalimumab of complex refractory fistulising Crohn disease by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has a documented history of complex refractory fistulising Crohn disease; and

(b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or infliximab for a draining enterocutaneous or rectovaginal fistula; and

(c) has not failed PBS-subsidised therapy with adalimumab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF- α antagonist therapy within the time frames specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF- α antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF- α antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF- α antagonist.

Authority applications must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and details of prior TNF- α antagonist treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum of 16 weeks treatment will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

Note

Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term 'tumour necrosis factor (TNF) α antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF- α antagonists at any 1 time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF- α antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF- α antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF- α antagonist treatment prior to 1 April 2011 is considered to be in their first cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF- α antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF- α antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF- α antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF- α antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF- α antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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	infliximab will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.							
	Note No applications for increased maximum quantities and/or repeats will be authorised.							
8965W	adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges	1	2	..	1774.70	37.70	Humira	VE
8963R	adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	1	2	..	1774.70	37.70	Humira	VE
8962Q	adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges	1	..	..	5036.70	37.70	Humira	VE
8961P	adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL syringes	1	..	..	5036.70	37.70	Humira	VE

ADALIMUMAB

Authority required

Initial 3 (grandfather)

Initial PBS-subsidised treatment of complex refractory FISTULISING CROHN DISEASE in a patient who has previously received non-PBS-subsidised therapy with adalimumab.

Initial PBS-subsidised supply for continuing treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who satisfies the following criteria:

(a) has a documented history of complex refractory fistulising Crohn disease and was receiving treatment with adalimumab prior to 4 November 2010; and

(b) had a draining enterocutaneous or rectovaginal fistula(e) prior to commencing treatment with adalimumab; and

(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) is receiving treatment with adalimumab at the time of application; and

(e) has demonstrated or sustained an adequate response to treatment with adalimumab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to adalimumab treatment is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current and baseline Fistula Assessment form including the date of assessment of the patient's condition; and

(ii) a signed patient acknowledgement.

The current fistula assessment must be no more than 1 month old at the time of application.

The baseline fistula assessment must be from immediately prior to commencing treatment with adalimumab.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

A maximum of 24 weeks treatment will be approved under this criterion.

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

Authority required

Continuing treatment of complex refractory FISTULISING CROHN DISEASE.

Continuing PBS-subsidised treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below or other

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of complex refractory fistulising Crohn disease; and

(b) has demonstrated or sustained an adequate response to treatment with adalimumab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The fistula assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with adalimumab, an assessment of the patient's response must be made following a minimum of 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

Patients are eligible to receive continuing adalimumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

A maximum of 24 weeks treatment will be authorised under this criterion.

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

Note

Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term 'tumour necrosis factor (TNF) alpha antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alpha antagonists at any 1 time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alpha antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alpha antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alpha antagonist treatment prior to 1 April 2011 is considered to be in their first cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alpha antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alpha antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alpha antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alpha antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alpha antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alpha antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	commence a new treatment cycle.						
	There is no limit to the number of treatment cycles a patient may undertake in their lifetime.						
	(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 April 2011.						
	(a) Initial treatment.						
	Applications for initial treatment should be made where:						
	(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or						
	(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or						
	(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).						
	Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.						
	From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.						
	Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.						
	For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.						
	Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.						
	(b) Continuing treatment.						
	Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.						
	It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.						
	Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.						
	Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.						
	(2) Swapping therapy.						
	Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle.						
	A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.						
	To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.						
	To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.						
	(3) Baseline measurements to determine response.						
	Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.						
	(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.						
	A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.						
	(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.						
	A patient who commenced treatment with adalimumab for complex refractory fistulising Crohn disease prior to 4 November 2010 or infliximab prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.						
	A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.						

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.							
	'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.							
	Note							
	No applications for increased maximum quantities and/or repeats will be authorised.							
8966X	adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges	1	5	..	1774.70	37.70	Humira	VE
8964T	adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	1	5	..	1774.70	37.70	Humira	VE

ADALIMUMAB

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have severe active rheumatoid arthritis,

AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months,

AND

Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times,

AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

intolerance and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

- (a) a total active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list of major joints:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note

No increase in the maximum quantity or number of units may be authorised.

No increase in the maximum number of repeats may be authorised.

Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

Special Pricing Arrangements apply

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

Reply Paid 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months)

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis,

AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy,

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

No increase in the maximum quantity or number of units may be authorised.

No increase in the maximum number of repeats may be authorised.

Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

Special Pricing Arrangements apply

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

[illegible]

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment,

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).								
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:								
Department of Human Services								
Prior Written Approval of Complex Drugs								
Reply Paid 9826								
GPO Box 9826								
HOBART TAS 7001								
9099X	adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges	1	3	..	1774.70	37.70	Humira	VE
8737W	adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	1	3	..	1774.70	37.70	Humira	VE

ADALIMUMAB

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis,

AND

Patient must have demonstrated an adequate response to treatment with this drug,

AND

Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction,

AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note

No increase in the maximum quantity or number of units may be authorised.

No increase in the maximum number of repeats may be authorised.

Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

Special Pricing Arrangements apply

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alpha antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2

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	infusions of rituximab.						
	A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course. Abatacept patients: Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application. Rituximab patients: A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate. (b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients: A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. (2) Swapping therapy. Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled. Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent. A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug. Abatacept patients: Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation. In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment. To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period. To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing. (3) Baseline measurements to determine response. the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response						

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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	according to these revised baseline measurements.							
	To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.							
	Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.							
	<u>Authority required</u>							
	Severe active rheumatoid arthritis							
	Treatment Phase: Continuing Treatment – balance of supply.							
	Clinical criteria:							
	Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment,							
	AND							
	The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.							
	Treatment criteria:							
	Must be treated by a rheumatologist; OR							
	Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.							
	<u>Note</u>							
	Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).							
	Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:							
	Department of Human Services							
	Prior Written Approval of Complex Drugs							
	Reply Paid 9826							
	HOBART TAS 7001							
9100Y	adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges	1	5	..	1774.70	37.70	Humira	VE
8741C	adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	1	5	..	1774.70	37.70	Humira	VE

ADALIMUMAB

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe active psoriatic arthritis,

AND

Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition,

AND

Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months,

AND

Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR

Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab. Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and either (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and (3) a signed patient acknowledgement. Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au) Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment. Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle. Note No increase in the maximum quantity or number of units may be authorised. Note No increase in the maximum number of repeats may be authorised. Authority required Severe psoriatic arthritis Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment) Clinical criteria: Patient must have a documented history of severe active psoriatic arthritis, AND Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, AND Patient must not receive more than 16 weeks of treatment under this restriction. Population criteria: Patient must be an adult. Treatment criteria: Must be treated by a rheumatologist: OR						

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form. Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug. Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased. Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased. Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment. Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle. Note No increase in the maximum quantity or number of units may be authorised. Note No increase in the maximum number of repeats may be authorised. Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis. Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only. Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements,						

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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	assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.							
	To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.							
	(4) Baseline measurements to determine response.							
	The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.							
	To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.							
	(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.							
	Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.							
	<u>Authority required</u>							
	Severe psoriatic arthritis							
	Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply							
	Clinical criteria:							
	Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR							
	Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 16 weeks treatment,							
	AND							
	The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.							
	Treatment criteria:							
	Must be treated by a rheumatologist; OR							
	Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.							
	<u>Note</u>							
	No increase in the maximum quantity or number of units may be authorised.							
	<u>Note</u>							
	No increase in the maximum number of repeats may be authorised.							
	<u>Note</u>							
	Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).							
	Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:							
	Department of Human Services							
	Prior Written Approval of Complex Drugs							
	Reply Paid 9826							
	GPO Box 9826							
	HOBART TAS 7001							
9101B	adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges	1	3	..	1774.70	37.70	Humira	VE
9033K	adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	1	3	..	1774.70	37.70	Humira	VE

ADALIMUMAB

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active psoriatic arthritis,

AND

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle,

AND

Patient must demonstrate, at the time of application, an adequate response to treatment with this drug,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Note

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle. To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing. (4) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints. (5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.							
	<u>Authority required</u> Severe psoriatic arthritis Treatment Phase: Continuing treatment - balance of supply Clinical criteria: Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Treatment criteria: Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Note No increase in the maximum quantity or number of units may be authorised. Note No increase in the maximum number of repeats may be authorised. Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001							
9102C	adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges	1	5	..	1774.70	37.70	Humira	VE
9034L	adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	1	5	..	1774.70	37.70	Humira	VE

ADALIMUMAB

Authority required

Active ankylosing spondylitis

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis,

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	AND Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab or infliximab in this treatment cycle, AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months. Population criteria: Patient must be an adult. Treatment criteria: Must be treated by a rheumatologist. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application. Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following: (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a completed BASDAI Assessment Form; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) a signed patient acknowledgment. The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment. A maximum of 16 weeks of treatment with this drug will be approved under this criterion. Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle. Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au Note No increase in the maximum quantity or number of units may be authorised. Note No increase in the maximum number of repeats may be authorised. Authority required Ankylosing spondylitis						

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	Treatment Phase: Initial 2 (change or recommencement for all patients)						
	Clinical criteria:						
	Patient must have a documented history of active ankylosing spondylitis,						
	AND						
	Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle,						
	AND						
	Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle,						
	AND						
	Patient must be eligible to receive further bDMARD therapy.						
	Population criteria:						
	Patient must be an adult.						
	Treatment criteria:						
	Must be treated by a rheumatologist.						
	Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.						
	Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.						
	The authority application must be made in writing and must include:						
	(a) a completed authority prescription form; and						
	(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.						
	A maximum of 16 weeks of treatment with this drug will be approved under this criterion.						
	Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.						
	Note						
	No increase in the maximum quantity or number of units may be authorised.						
	Note						
	No increase in the maximum number of repeats may be authorised.						
	Note						
	Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).						
	Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au						
	Applications for authority to prescribe should be forwarded to:						
	Department of Human Services						
	Prior Written Approval of Complex Drugs						
	Reply Paid 9826						
	GPO Box 9826						
	HOBART TAS 7001						
	Note						
	TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS						
	The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.						
	Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.						
	A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.						
	From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.						
	A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.						

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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	Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle. A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle. A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle. There is no limit to the number of treatment cycles a patient may undertake in their lifetime. (1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010. (a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or (ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2). A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course. (b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. (2) Swapping therapy. Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements. A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing. (3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements. For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. (4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.						

Authority required

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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	Ankylosing spondylitis							
	Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply							
	Clinical criteria:							
	Patient must have active, or a documented history of active, ankylosing spondylitis,							
	AND							
	Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 16 weeks treatment; OR							
	Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 16 weeks treatment,							
	AND							
	The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.							
	Population criteria:							
	Patient must be an adult.							
	Treatment criteria:							
	Must be treated by a rheumatologist.							
	<u>Note</u>							
	No increase in the maximum quantity or number of units may be authorised.							
	<u>Note</u>							
	No increase in the maximum number of repeats may be authorised.							
	<u>Note</u>							
	Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).							
	Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:							
	Department of Human Services							
	Prior Written Approval of Complex Drugs							
	Reply Paid 9826							
	GPO Box 9826							
	HOBART TAS 7001							
9103D	adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges	1	3	..	1774.70	37.70	Humira	VE
9077R	adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	1	3	..	1774.70	37.70	Humira	VE

ADALIMUMAB

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of active ankylosing spondylitis,

AND

Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,

AND

Patient must have demonstrated an adequate response to treatment with this drug.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.

Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

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(iii)	a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).						
	A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.						
	Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.						
	For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.						
(b)	Continuing treatment.						
	Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.						
	It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.						
(2)	Swapping therapy.						
	Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.						
	A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.						
	To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.						
	To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.						
(3)	Baseline measurements to determine response.						
	The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.						
	For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.						
	To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.						
(4)	Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.						
	A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.						
	<u>Authority required</u>						
	Ankylosing spondylitis						
	Treatment Phase: Continuing treatment – balance of supply						
	Clinical criteria:						
	Patient must have a documented history of active ankylosing spondylitis,						
	AND						
	Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment,						
	AND						
	The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.						
	Population criteria:						
	Patient must be an adult.						
	Treatment criteria:						
	Must be treated by a rheumatologist.						
	Note						
	No increase in the maximum quantity or number of units may be authorised.						
	Note						
	No increase in the maximum number of repeats may be authorised.						
	Note						

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001							
9104E	adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges	1	5	..	1774.70	37.70	Humira	VE
9078T	adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	1	5	..	1774.70	37.70	Humira	VE

ADALIMUMAB

Authority required

Initial 1 (new patients)

Initial treatment of Crohn disease in a patient assessed by CDAI.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:

- (a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and
- (b) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
- (c) has failed to achieve an adequate response to prior systemic therapy including:
 - (i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
 - (ii) immunosuppressive therapy including:
 - azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
 - 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
 - methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

- (a) have a severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as assessed.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

The most recent CDAI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

- (a) two completed authority prescription forms; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition; and
 - (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
 - (iii) the signed patient acknowledgement.

A maximum of 16 weeks treatment will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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A CDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

Authority required

Initial 2

Change or re-commencement of treatment of Crohn disease in a patient assessed by CDAI.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:

- (a) has a documented history of severe refractory Crohn disease; and
- (b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and
- (c) has not failed PBS-subsidised therapy with adalimumab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

- (a) two completed authority prescription forms; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) the completed current Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; and
 - (ii) details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

Authority required

Initial 1

Initial treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist, or consultant physician as specified in the NOTE below of a patient who satisfies the following criteria:

- (a) has confirmed Crohn disease defined by standard clinical, endoscopic and/or imaging features, including histological evidence with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and
- (b) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy; and
- (c) has evidence of intestinal inflammation; and
- (d) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
- (e) has failed to achieve an adequate response to prior systemic drug therapy including:
 - (i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

(ii) immunosuppressive therapy including:

- azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
- 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
- methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) have evidence of intestinal inflammation, including:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR

(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;

AND/OR

(b) be assessed clinically as being in a high faecal output state;

AND/OR

(c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of adalimumab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(ii) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iii) date of the most recent clinical assessment; and

(iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum of 16 weeks treatment will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

Authority required

Initial 2

Change or re-commencement of treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient or a patient with extensive small intestine disease.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

(a) has a documented history of severe refractory Crohn disease; and

(b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and

(c) has not failed PBS-subsidised therapy with adalimumab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criteria, if relevant; and

(ii) details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

A maximum of 16 weeks of treatment will be approved under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

Authority required

Initial 1

Initial treatment of Crohn disease in a patient with extensive small intestine disease.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and

(b) has extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; and

(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) has failed to achieve an adequate response to prior systemic therapy including:

(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and

(ii) immunosuppressive therapy including:

— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or

— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or

— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

application:

(a) have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220;

AND/OR

(b) have evidence of active intestinal inflammation, including:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR

(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;

AND/OR

(c) be assessed clinically as being in a high faecal output state;

AND/OR

(d) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of adalimumab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(ii) (1) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; or

(2) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the dates of assessment of the patient's condition, if relevant; and

(iii) date of the most recent clinical assessment; and

(iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum of 16 weeks treatment of adalimumab will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy after the first dose so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

Note

Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE REFRACTORY CROHN DISEASE

[illegible]

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	treatment with that drug two times within the same treatment cycle.							
	To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.							
	To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.							
	(3) Baseline measurements to determine response.							
	Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.							
	To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.							
	(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.							
	A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.							
	(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.							
	A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 9 November 2007 or infliximab prior to 7 March 2007 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.							
	A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.							
	Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.							
	'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.							
	Note							
	No applications for increased maximum quantities and/or repeats will be authorised.							
9190Q	adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges	1	2	..	1774.70	37.70	Humira	VE
9188N	adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	1	2	..	1774.70	37.70	Humira	VE
9187M	adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges	1	..	..	5036.70	37.70	Humira	VE
9186L	adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL syringes	1	..	..	5036.70	37.70	Humira	VE

ADALIMUMAB

Authority required

Initial 3 (grandfather)

Initial PBS-subsidised treatment of Crohn disease in a patient assessed by CDAI who has previously received non-PBS-subsidised therapy with adalimumab.

Initial PBS-subsidised supply for continuing treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who:

(a) has a documented history of severe refractory Crohn disease and was receiving treatment with adalimumab prior to 9 November 2007; and

(b) had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with adalimumab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and

(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) has demonstrated or sustained an adequate response to treatment with adalimumab. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to adalimumab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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(www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; and

(ii) the signed patient acknowledgement.

The current CDAI assessment must be no more than 1 month old at the time of application. The baseline CDAI assessment must be from immediately prior to commencing treatment with adalimumab.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

A maximum of 24 weeks treatment will be approved under this criterion.

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

Authority required

Continuing treatment of Crohn disease in a patient assessed by CDAI.

Continuing PBS-subsidised treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of severe refractory Crohn disease; and

(b) has demonstrated or sustained an adequate response to treatment with adalimumab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to adalimumab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition.

The CDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with adalimumab, a CDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

Patients are eligible to receive continuing adalimumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

A maximum of 24 weeks treatment will be authorised under this criterion.

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

Authority required

Continuing treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Continuing PBS-subsidised treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of severe refractory Crohn disease with intestinal inflammation and with short gut syndrome or with an ileostomy or colostomy; and

(b) has demonstrated or sustained an adequate response to treatment with adalimumab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to adalimumab treatment is defined as:

(a) improvement of intestinal inflammation as demonstrated by:

(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive

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	protein (CRP) level no greater than 15 mg per L; AND/OR (ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN). Applications for authorisation must be made in writing and must include: (a) a completed authority prescription; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following: (i) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy or the date of clinical assessment. The patient's assessment must be no more than 1 month old at the time of application. If the application is the first application for continuing treatment with adalimumab, an assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy after the first dose so that there is adequate time for a response to be demonstrated. The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion. Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab. Patients are eligible to receive continuing adalimumab treatment in courses of up to 24 weeks providing they continue to sustain the response. A maximum of 24 weeks of treatment will be authorised under this criterion. Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)						
	Authority required Continuing treatment of Crohn disease in a patient with extensive small intestine disease. Continuing PBS-subsidised treatment with adalimumab by a gastroenterologist, or consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who: (a) has a documented history of severe refractory Crohn disease with extensive intestinal inflammation affecting more than 50 cm of the small intestine; and (b) has demonstrated or sustained an adequate response to treatment with adalimumab. NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)]. An adequate response to adalimumab treatment is defined as: (a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or (b) improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR (ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (c) reversal of high faecal output state; or (d) avoidance of the need for surgery or total parenteral nutrition (TPN). Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following: (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; or (ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy; or (iii) the date of clinical assessment. All assessments must be no more than 1 month old at the time of application. If the application is the first application for continuing treatment with adalimumab, an assessment of the patient's response must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated. The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.						

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

[illegible]

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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A maximum of 24 weeks treatment will be authorised under this criterion.

Where fewer than 5 repeats are requested at the time of this application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

Note

Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for adult patients with severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 August 2008, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2008 is considered to be in their first cycle as of 1 August 2008.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2008.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. (b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply. Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist. (2) Swapping therapy. Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, evidence of intestinal inflammation), or the prior corticosteroid therapy and immunosuppressive therapy. A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing. (3) Baseline measurements to determine response. Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. (4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured. (5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab. A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 9 November 2007 or infliximab prior to 7 March 2007 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.						
Note							
No applications for increased maximum quantities and/or repeats will be authorised.							
9191R	adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges	1	5	..	1774.70	37.70	Humira VE
9189P	adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	1	5	..	1774.70	37.70	Humira VE

Note

No applications for increased maximum quantities and/or repeats will be authorised.

ADALIMUMAB

Authority required

Initial treatment [Initial 1, Whole body (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and

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	(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and (c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); and (d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks. If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au). The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application: (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment. (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment. (c) The most recent PASI assessment must be no more than 1 month old at the time of application. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following: (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] and (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and (iii) the signed patient and prescriber acknowledgements. A maximum of 16 weeks of treatment with adalimumab will be authorised under this restriction. Where fewer than 4 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks. A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss. It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment						
	Authority required Initial or re-Treatment [Initial 2, Whole body (Received prior biological agent under PBS)] Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who: (a) have a documented history of severe chronic plaque psoriasis; and (b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and (c) have not failed PBS-subsidised therapy with adalimumab for the treatment of this condition in the current Treatment Cycle. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following: (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] and (ii) details of prior biological treatment, including dosage, date and duration of treatment. Applications for patients who have demonstrated a response to PBS-subsidised adalimumab treatment within this Treatment Cycle and who wish to						

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	A maximum of 16 weeks of treatment with adalimumab will be authorised under this restriction.						
	Where fewer than 4 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.						
	A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.						
	It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.						
	The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline						
	<u>Authority required</u>						
	Initial or re-Treatment [Initial 2, Face, hand, foot (Received prior biological agent under PBS)]						
	Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:						
	(a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and						
	(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and						
	(c) have not failed PBS-subsidised therapy with adalimumab for the treatment of this condition in the current Treatment Cycle.						
	Applications for authorisation must be made in writing and must include:						
	(a) a completed authority prescription form; and						
	(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:						
	(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and						
	(ii) details of prior biological treatment, including dosage, date and duration of treatment.						
	Applications for patients who have demonstrated a response to PBS-subsidised adalimumab treatment within this Treatment Cycle and who wish to re-commence adalimumab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised adalimumab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.						
	A maximum of 16 weeks of treatment with adalimumab will be authorised under this restriction.						
	Where fewer than 4 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.						
	A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.						
	It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.						
	The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.						
	Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle						
	Note						
	Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).						
	Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au .						
	Written applications for authority to prescribe adalimumab should be forwarded to:						
	Medicare Australia						
	Prior Written Approval of Specialised Drugs						
	Reply Paid 9826						
	GPO Box 9826						

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab and ustekinumab.

From 1 March 2010, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept, infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 March 2010 is considered to be in their first Cycle as of 1 March 2010.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 March 2010, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2010.

Patients must be assessed for response to each course of continuing treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 March 2010.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or
- (iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept, infliximab or ustekinumab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.							
	Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.							
	Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.							
	Patients who commenced treatment with adalimumab prior to 1 June 2009 or ustekinumab prior to 1 March 2010 access these interchangeability arrangements in the same way as patients who have not.							
	To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.							
	To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.							
	(5) Baseline measurements to determine response.							
	Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.							
	To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.							
	(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.							
	Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.							
	Note No applications for increased maximum quantities and/or repeats will be authorised.							
	Note Special Pricing Arrangements apply.							
9426D	adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges	1	4	..	1774.70	37.70	Humira	VE
9425C	adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	1	4	..	1774.70	37.70	Humira	VE

ADALIMUMAB

Authority required

Continuing treatment (Whole body)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

- (a) who have a documented history of severe chronic plaque psoriasis; and
- (b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with adalimumab; and
- (c) who have demonstrated an adequate response to their most recent course of treatment with adalimumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-biological treatment baseline value for this Treatment Cycle.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet along with the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with adalimumab.

A maximum of 24 weeks of treatment with adalimumab will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

Authority required

Continuing treatment (Face, hand, foot)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

- (a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and
- (b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with adalimumab; and
- (c) who have demonstrated an adequate response to treatment with adalimumab.

An adequate response to adalimumab treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

The most recent PASI assessment must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with adalimumab will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

Note

Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab and ustekinumab.

From 1 March 2010, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept, infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 March 2010 is considered to be in their first Cycle as of 1 March 2010.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 March 2010, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2010.

Patients must be assessed for response to each course of continuing treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 March 2010.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or
- (iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept, infliximab or ustekinumab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

Patients who commenced treatment with adalimumab prior to 1 June 2009 or ustekinumab prior to 1 March 2010 access these interchangeability arrangements in the same way as patients who have not.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

Note

Special Pricing Arrangements apply.

9428F	adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges	1	5	..	1774.70	37.70	Humira	VE
9427E	adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	1	5	..	1774.70	37.70	Humira	VE

CERTOLIZUMAB PEGOL

Authority required

Active ankylosing spondylitis

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis,

AND

Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab or infliximab in this treatment cycle,

AND

Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender,

AND

Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

The application must include details of the NSAIDs trialed, their doses and duration of treatment.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application. Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following: (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a completed BASDAI Assessment Form; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) a signed patient acknowledgment. The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment. A maximum of 18 to 20 weeks of treatment with this drug will be approved under this criterion. Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle. Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au Note No increase in the maximum quantity or number of units may be authorised. Note No increase in the maximum number of repeats may be authorised. Authority required Ankylosing spondylitis Treatment Phase: Initial 2 (change or recommencement for all patients) Clinical criteria: Patient must have a documented history of active ankylosing spondylitis, AND Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, AND Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, AND Patient must be eligible to receive further bDMARD therapy. Population criteria: Patient must be an adult. Treatment criteria: Must be treated by a rheumatologist. Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patient						

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 18 to 20 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.

Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

Clinical criteria:

Patient must have active, or a documented history of active, ankylosing spondylitis,

AND

Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 18 to 20 weeks treatment;
OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 18 to 20 weeks treatment,

AND

The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

Note

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

Authority approval for sufficient therapy to complete a maximum of 18 to 20 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 18 to 20 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of active ankylosing spondylitis,

AND

Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,

AND

Patient must have demonstrated an adequate response to treatment with this drug.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.

Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing. (3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements. For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. (4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured. <u>Authority required</u> Ankylosing spondylitis Treatment Phase: Continuing treatment – balance of supply Clinical criteria: Patient must have a documented history of active ankylosing spondylitis, AND Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Population criteria: Patient must be an adult. Treatment criteria: Must be treated by a rheumatologist. <u>Note</u> No increase in the maximum quantity or number of units may be authorised. <u>Note</u> No increase in the maximum number of repeats may be authorised. <u>Note</u> Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001						
10137M	certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes	1	5	..	1708.98	37.70	Cimzia UC

CERTOLIZUMAB PEGOL

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe active psoriatic arthritis,

AND

Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition,

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	AND						
	Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months,						
	AND						
	Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR						
	Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months,						
	AND						
	Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.						
	Population criteria:						
	Patient must be an adult.						
	Treatment criteria:						
	Must be treated by a rheumatologist; OR						
	Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.						
	For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.						
	Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.						
	Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.						
	The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:						
	an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and either						
	(a) an active joint count of at least 20 active (swollen and tender) joints; or						
	(b) at least 4 active joints from the following list of major joints:						
	(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or						
	(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).						
	If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.						
	The authority application must be made in writing and must include:						
	(1) a completed authority prescription form; and						
	(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and						
	(3) a signed patient acknowledgement.						
	Note						
	Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)						
	Note						
	The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.						
	Note						
	Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.						
	Note						
	No increase in the maximum quantity or number of units may be authorised.						
	Note						
	No increase in the maximum number of repeats may be authorised.						
	Note						
	Special Pricing Arrangements apply.						
	Authority required						
	Severe psoriatic arthritis						
	Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)						
	Clinical criteria:						

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	Patient must have a documented history of severe active psoriatic arthritis, AND Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction. Population criteria: Patient must be an adult. Treatment criteria: Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form. Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug. Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased. Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased. Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment. Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle. Note No increase in the maximum quantity or number of units may be authorised. Note No increase in the maximum number of repeats may be authorised. Note Special Pricing Arrangements apply. Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of						

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing

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	treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent. (3) Swapping therapy. Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not. Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing: (i) they have not received PBS-subsidised treatment with that particular biological agent previously; or (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle. To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing. (4) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints. (5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured. <u>Authority required</u> Severe psoriatic arthritis Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply <u>Clinical criteria:</u> Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 18 to 20 weeks treatment; OR Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 18 to 20 weeks treatment, <u>AND</u> The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions. <u>Treatment criteria:</u> Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. <u>Note</u> No increase in the maximum quantity or number of units may be authorised. <u>Note</u> No increase in the maximum number of repeats may be authorised. <u>Note</u> Special Pricing Arrangements apply. <u>Note</u> Authority approval for sufficient therapy to complete a maximum of 18 to 20 weeks of treatment may be requested by telephone by contacting the						

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	Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written application for authority approval for sufficient therapy to complete a maximum of 18 to 20 weeks of treatment should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 <u>Authority required</u> Severe psoriatic arthritis Treatment Phase: Initial treatment - Initial 3 (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) Clinical criteria: Patient must have a documented history of severe active psoriatic arthritis, AND Patient must have been receiving treatment with certolizumab pegol for this condition prior to 1 April 2015, AND Patient must be receiving treatment with certolizumab pegol at the time of application, AND Patient must have demonstrated a response to treatment as specified in the criteria for continuing PBS-subsidised treatment with certolizumab pegol, AND Patient must not receive more than 24 weeks of treatment under this restriction. Population criteria: Patient must be an adult. Treatment criteria: Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and (3) a signed patient acknowledgement. A patient may qualify for PBS-subsidised treatment under this restriction once only. <u>Note</u> The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment. <u>Note</u> Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle. <u>Note</u> No increase in the maximum quantity or number of units may be authorised. <u>Note</u> No increase in the maximum number of repeats may be authorised. <u>Note</u> Special Pricing Arrangements apply. <u>Note</u> Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs						

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
- (iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - certolizumab pegol only.

For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes,

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
- (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 3 (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) restriction to complete 24 weeks treatment,

AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

Special Pricing Arrangements apply.

Note

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

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GPO Box 9826

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active psoriatic arthritis,

AND

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle,

AND

Patient must demonstrate, at the time of application, an adequate response to treatment with this drug,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Note

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

Special Pricing Arrangements apply.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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Department of Human Services

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Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
- (iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - certolizumab pegol only.

For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

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	Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent. (3) Swapping therapy. Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not. Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing: (i) they have not received PBS-subsidised treatment with that particular biological agent previously; or (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle. To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing. (4) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints. (5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured. <u>Authority required</u> Severe psoriatic arthritis Treatment Phase: Continuing treatment - balance of supply Clinical criteria: Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Treatment criteria: Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. <u>Note</u> No increase in the maximum quantity or number of units may be authorised. <u>Note</u> No increase in the maximum number of repeats may be authorised. <u>Note</u> Special Pricing Arrangements apply. <u>Note</u> Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826						

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
10238W	HOBART TAS 7001 certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes	1	5	..	1708.98	37.70	Cimzia	UC

CERTOLIZUMAB PEGOL

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have severe active rheumatoid arthritis,

AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months,

AND

Patient must not have not failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times.,

AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly,

AND

Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction..

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;

(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;

(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note

Special Pricing Arrangements apply.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

[illegible]

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. (2) Swapping therapy. Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled. Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent. A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug. Abatacept patients: Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation. In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment. To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period. To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing. (3) Baseline measurements to determine response. the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. <u>Authority required</u> Severe active rheumatoid arthritis Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months). Clinical criteria: Patient must have a documented history of severe active rheumatoid arthritis, AND Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.. Population criteria: Patient must be aged 18 years or older. Treatment criteria: Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.						

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	For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab. The authority application must be made in writing and must include: (a) a completed authority prescription form and (b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. Application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased. Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased. If a patient fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 HOBART TAS 7001 Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept). Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time. In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist. A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements: - a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, - a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and - once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis. For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify						

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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	Abatacept patients: Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation. In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment. To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period. To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing. (3) Baseline measurements to determine response. the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. <u>Authority required</u> Severe active rheumatoid arthritis Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply. Clinical criteria: Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen; OR Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen, AND The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions. Treatment criteria: Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. <u>Note</u> Authority approval for sufficient therapy to complete a maximum of 18-20 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written application for authority approval for sufficient therapy to complete a maximum of 18-20 weeks of treatment should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 HOBART TAS 7001 <u>Authority required</u> Severe active rheumatoid arthritis Treatment Phase: Continuing treatment Clinical criteria: Patient must have a documented history of severe active rheumatoid arthritis, AND						

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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Patient must have demonstrated an adequate response to treatment with this drug,

AND

Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

course of treatment with a PBS-subsidised TNF- α antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF- α antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment,

AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	HOBART TAS 7001						
3425G	certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes	1	5	..	1708.98	37.70	Cimzia UC

ETANERCEPT

Authority required

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment (whole body)

Clinical criteria:

The treatment must be as systemic monotherapy; OR

The treatment must be in combination with methotrexate,

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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AND

Patient must have lesions present for at least 6 months from the time of initial diagnosis,

AND

Patient must not have received any prior PBS-subsidised treatment with etanercept for this condition; OR

Patient must not have received any PBS-subsidised treatment with etanercept for this condition for at least 12 months,

AND

Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; and/or (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks,

AND

Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

Population criteria:

Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

Treatment criteria:

Must be treated by a dermatologist.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in a patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the parent or authorised guardian signed patient and prescriber acknowledgements.

Where a patient has had a 12 month treatment break, the length of the break is measured from the date the most recent treatment was stopped to the date of the application to re-commence treatment.

Note

Details of acceptable toxicities including severity, associated with phototherapy, methotrexate and acitretin, can be found on the Department of Human Services website at www.humanservices.gov.au

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

Note

Special Pricing Arrangements apply.

Authority required

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

- (i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or
- (ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

- (i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR
- (ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment or Re-treatment (Whole body) - balance of first supply

Clinical criteria:

The treatment must be as systemic monotherapy; OR

The treatment must be in combination with methotrexate,

AND

Patient must have received insufficient therapy under the Initial treatment (whole body) restriction for severe chronic plaque psoriasis to complete

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	16 weeks treatment; OR Patient must have received insufficient therapy under the Re-treatment (whole body) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment, AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. Treatment criteria: Must be treated by a dermatologist. Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 Note No increase in the maximum quantity or number of units may be authorised. Note No increase in the maximum number of repeats may be authorised. Note Special Pricing Arrangements apply. Authority required TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis. Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone. Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment. There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet. (1) Application for approval for initial treatment. Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy. (2) Applications for approval for re-treatment. Applications for re-treatment with etanercept should be made in the following situations: (i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or (ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy. For psoriasis affecting the whole body: Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept. For psoriasis affecting the face, hand or foot: Patients are eligible for re-treatment due to disease flare if: (i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR (ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept. (3) Applications for approval for completion of a course Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment. The PASI assessment must be conducted after at least 12 weeks of treatment.						

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss. (4) Baseline measurements to determine response. The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score. To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment. (5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy. A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application. Severe chronic plaque psoriasis Treatment Phase: Initial treatment or Re-treatment (Whole body) - completion of course Clinical criteria: The treatment must be as systemic monotherapy; OR The treatment must be in combination with methotrexate, AND Patient must have received 16 weeks treatment under the Initial treatment (whole body) restriction for severe chronic plaque psoriasis; OR Patient must have received 16 weeks treatment under the Re-treatment (whole body) restriction for severe chronic plaque psoriasis, AND Patient must have demonstrated an adequate response to treatment, AND Patient must not receive more than 8 weeks of treatment with etanercept under this restriction. Treatment criteria: Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, when compared with the pre-etanercept treatment baseline value. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of assessment of the patient's condition. The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment. A PASI assessment of the patient's response to the initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for a further 8 weeks of treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their initial 16 week treatment course to ensure continuity of treatment for those patients who meet the eligibility criterion for a further 8 weeks of PBS-subsidised etanercept treatment. Note In circumstances where it is not possible to submit a response assessment after 12 weeks of treatment, please call the Department of Human Services on 1800 700 270 to discuss. Note The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to:						

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

Special Pricing Arrangements apply.

Authority required

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	at least 12 months , must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.						
	Severe chronic plaque psoriasis						
	Treatment Phase: Re-treatment (Whole body)						
	Clinical criteria:						
	The treatment must be as systemic monotherapy; OR						
	The treatment must be in combination with methotrexate,						
	AND						
	Patient must have a documented history of severe chronic plaque psoriasis of the whole body,						
	AND						
	Patient must have received prior PBS-subsidised treatment with etanercept for this condition in the past 12 months,						
	AND						
	Patient must have demonstrated a response to etanercept and experienced a disease flare; OR						
	Patient must not have failed more than once to achieve an adequate response with etanercept,						
	AND						
	Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.						
	Population criteria:						
	Patient must be under 18 years of age.						
	Treatment criteria:						
	Must be treated by a dermatologist.						
	A patient is eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.						
	The authority application must be made in writing and must include:						
	(a) a completed authority prescription form; and						
	(b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information which includes the following:						
	(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and						
	(ii) details of prior etanercept treatment, including date ceased.						
	Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.						
	Note						
	Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).						
	Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au						
	Applications for authority to prescribe should be forwarded to:						
	Department of Human Services						
	Prior Written Approval of Complex Drugs						
	Reply Paid 9826						
	GPO Box 9826						
	HOBART TAS 7001						
	Note						
	No increase in the maximum quantity or number of units may be authorised.						
	Note						
	No increase in the maximum number of repeats may be authorised.						
	Note						
	Special Pricing Arrangements apply.						
	Authority required						
	TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS						
	The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.						
	Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A						

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone. Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment. There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet. (1) Application for approval for initial treatment. Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy. (2) Applications for approval for re-treatment. Applications for re-treatment with etanercept should be made in the following situations: (i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or (ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy. For psoriasis affecting the whole body: Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept. For psoriasis affecting the face, hand or foot: Patients are eligible for re-treatment due to disease flare if: (i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR (ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept. (3) Applications for approval for completion of a course Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment. The PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss. (4) Baseline measurements to determine response. The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score. To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment. (5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy. A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application. Severe chronic plaque psoriasis Treatment Phase: Initial treatment (Face, hand, foot) Clinical criteria: The treatment must be as systemic monotherapy; OR The treatment must be in combination with methotrexate, AND Patient must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis, AND Patient must not have received any prior PBS-subsidised treatment with etanercept for this condition; OR Patient must not have received any PBS-subsidised treatment with etanercept for this condition for at least 12 months, AND Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; and/or (iii) acitretin at a dose of at least 0.4 mg per kg per						

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

day for at least 6 weeks,

AND

Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

Population criteria:

Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

Treatment criteria:

Must be treated by a dermatologist.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in a patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and face, hand, foot area diagrams including the dates of assessment of the patient's condition

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the parent or authorised guardian signed patient and prescriber acknowledgements.

Where a patient has had a 12 month treatment break, the length of the break is measured from the date the most recent treatment was stopped to the date of the application to re-commence treatment.

Note

Details of acceptable toxicities including severity, associated with phototherapy, methotrexate and acitretin, can be found on the Department of Human Services website at www.humanservices.gov.au

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

Special Pricing Arrangements apply.

Authority required

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone. Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment. There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet. (1) Application for approval for initial treatment. Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy. (2) Applications for approval for re-treatment. Applications for re-treatment with etanercept should be made in the following situations: (i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or (ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy. For psoriasis affecting the whole body: Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept. For psoriasis affecting the face, hand or foot: Patients are eligible for re-treatment due to disease flare if: (i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR (ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept. (3) Applications for approval for completion of a course Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment. The PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss. (4) Baseline measurements to determine response. The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score. To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment. (5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy. A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application. Severe chronic plaque psoriasis Treatment Phase: Initial treatment of Re-treatment (Face, hand, foot) - balance of first supply Clinical criteria: The treatment must be as systemic monotherapy; OR The treatment must be in combination with methotrexate, AND Patient must have received insufficient therapy under the Initial treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment; OR Patient must have received insufficient therapy under the Re-treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment, AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. Treatment criteria:						

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

Must be treated by a dermatologist.

Note

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

Special Pricing Arrangements apply.

Authority required

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

- (i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or
- (ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

- (i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR
- (ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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	authority is submitted and subsequent response will be assessed according to this revised PASI score.						
	To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.						
	(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.						
	A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.						
	Severe chronic plaque psoriasis						
	Treatment Phase: Initial treatment or Re-treatment (Face, hand, foot) - completion of course						
	Clinical criteria:						
	The treatment must be as systemic monotherapy; OR						
	The treatment must be in combination with methotrexate,						
	AND						
	Patient must have received 16 weeks treatment under the Initial treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis; OR						
	Patient must have received 16 weeks treatment under the Re-treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis,						
	AND						
	Patient must have demonstrated an adequate response to treatment,						
	AND						
	Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.						
	Treatment criteria:						
	Must be treated by a dermatologist.						
	An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:						
	(i) a reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or						
	(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.						
	The authority application must be made in writing and must include:						
	(a) a completed authority prescription form; and						
	(b) the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of assessment of the patient's condition.						
	The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.						
	A PASI assessment of the patient's response to the initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for a further 8 weeks of treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.						
	Note						
	It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their initial 16 week treatment course to ensure continuity of treatment for those patients who meet the eligibility criterion for a further 8 weeks of PBS-subsidised etanercept treatment.						
	Note						
	In circumstances where it is not possible to submit a response assessment after 12 weeks of treatment, please call the Department of Human Services on 1800 700 270 to discuss.						
	Note						
	The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept.						
	Note						
	Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).						
	Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au						
	Applications for authority to prescribe should be forwarded to:						
	Department of Human Services						
	Prior Written Approval of Complex Drugs						
	Reply Paid 9826						
	GPO Box 9826						
	HOBART TAS 7001						

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

Special Pricing Arrangements apply.

Authority required

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Severe chronic plaque psoriasis

Treatment Phase: Re-treatment (Face, hand, foot)

Clinical criteria:

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	The treatment must be as systemic monotherapy; OR The treatment must be in combination with methotrexate, AND Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, AND Patient must have received prior PBS-subsidised treatment with etanercept for this condition in the past 12 months, AND Patient must have demonstrated a response to etanercept and experienced a disease flare; OR Patient must not have failed more than once to achieve an adequate response with etanercept, AND Patient must not receive more than 16 weeks of treatment with etanercept under this restriction. Population criteria: Patient must be under 18 years of age. Treatment criteria: Must be treated by a dermatologist. A patient is eligible for re-treatment due to disease flare if: (i) all subscores are rated moderate to severe or 2 of the 3 subscores are rated severe to very severe; or (ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept. The authority application must be made in writing and must include : (a) a completed authority prescription form; and (b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information which includes the following: (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area digrams including the dates of assessment of the patient's condition; and (ii) details of prior etanercept treatment, including date ceased. Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment. Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 Note No increase in the maximum quantity or number of units may be authorised. Note No increase in the maximum number of repeats may be authorised. Note Special Pricing Arrangements apply.							
1964J	ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1	1	3	..	1774.71	37.70	Enbrel	PF
1963H	ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1	1	3	..	1774.71	37.70	Enbrel	PF
1954W	etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack	2	3	..	*1774.70	37.70	Enbrel	PF

ETANERCEPT
Authority required

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	Severe active juvenile idiopathic arthritis						
	Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)						
	Clinical criteria:						
	Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years,						
	AND						
	Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months; OR						
	Patient must have received no PBS-subsidised bDMARD treatment for at least 5 years if they failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) in their last treatment cycle,						
	AND						
	Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR						
	Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR						
	Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly,						
	AND						
	Patient must not receive more than 16 weeks of treatment under this restriction.						
	Population criteria:						
	Patient must be aged 18 years or older.						
	Treatment criteria:						
	Must be treated by a rheumatologist; OR						
	Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.						
	For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.						
	If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.						
	The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.						
	The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.						
	If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.						
	The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:						
	an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either						
	(a) an active joint count of at least 20 active (swollen and tender) joints; or						
	(b) at least 4 active joints from the following list:						
	(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or						

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle.

Note

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle. A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle. There is no limit to the number of treatment cycles a patient may undertake. (1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014. (a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2). Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy. A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course. (b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. (2) Swapping therapy. Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing. (3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement. (4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy. A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.						

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 24 months)

Clinical criteria:

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years,

AND

Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle,

AND

Patient must not have failed PBS-subsidised therapy with etanercept for this condition in the current treatment cycle,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has received PBS-subsidised treatment with etanercept in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised etanercept treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

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 GPO Box 9826
 HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

[illegible]

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply

Clinical criteria:

Patient must have received insufficient etanercept therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient etanercept therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment,

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

3447K	ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1	1	3	..	1774.71	37.70	Enbrel	PF
3446J	ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1	1	3	..	1774.71	37.70	Enbrel	PF
3445H	etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack	2	3	..	*1774.70	37.70	Enbrel	PF

ETANERCEPT

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years,

AND

Patient must have demonstrated an adequate response to treatment with etanercept,

AND

Patient must have received etanercept as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

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Prior Written Approval of Complex Drugs

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Note

TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

[illegible]

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.							
	A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.							
	Authority required							
	Severe active juvenile idiopathic arthritis							
	Treatment Phase: Continuing treatment – balance of supply							
	Clinical criteria:							
	Patient must have received insufficient etanercept therapy under the Continuing treatment restriction to complete 24 weeks treatment,							
	AND							
	The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.							
	Treatment criteria:							
	Must be treated by a rheumatologist; OR							
	Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.							
	Note							
	Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).							
	Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:							
	Department of Human Services							
	Prior Written Approval of Complex Drugs							
	Reply Paid 9826							
	GPO Box 9826							
	HOBART TAS 7001							
3450N	ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1	1	5	..	1774.71	37.70	Enbrel	PF
3449M	ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1	1	5	..	1774.71	37.70	Enbrel	PF
3448L	etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack	2	5	..	*1774.70	37.70	Enbrel	PF
	ETANERCEPT							
	Authority required							
	Active ankylosing spondylitis							
	Treatment Phase: Initial 1 (new patients)							
	Clinical criteria:							
	The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis,							
	AND							
	Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab or infliximab in this treatment cycle,							
	AND							
	Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender,							
	AND							
	Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.							
	Population criteria:							
	Patient must be an adult.							
	Treatment criteria:							
	Must be treated by a rheumatologist.							
	The application must include details of the NSAIDs trialled, their doses and duration of treatment.							
	If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.							
	If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of							

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) a signed patient acknowledgment.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

Note

Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

Note

For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial 2 (change or recommencement for all patients)

Clinical criteria:

Patient must have a documented history of active ankylosing spondylitis,

AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle,

AND

Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle,

AND

Patient must be eligible to receive further bDMARD therapy.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.

Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

Clinical criteria:

Patient must have active, or a documented history of active, ankylosing spondylitis,

AND

Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 16 weeks treatment,

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001							
9455P	ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1	1	3	..	1774.71	37.70	Enbrel	PF
9085E	ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1	1	3	..	1774.71	37.70	Enbrel	PF
8778B	etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack	2	3	..	*1774.70	37.70	Enbrel	PF

ETANERCEPT

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of active ankylosing spondylitis,

AND

Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,

AND

Patient must have demonstrated an adequate response to treatment with this drug.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	8 a.m. to 5 p.m. EST Monday to Friday).						
	Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au						
	Applications for authority to prescribe should be forwarded to:						
	Department of Human Services						
	Prior Written Approval of Complex Drugs						
	Reply Paid 9826						
	GPO Box 9826						
	HOBART TAS 7001						
	Note						
	TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS						
	The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.						
	Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.						
	A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.						
	From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.						
	A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.						
	Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.						
	Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.						
	A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.						
	A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.						
	There is no limit to the number of treatment cycles a patient may undertake in their lifetime.						
	(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.						
	(a) Initial treatment.						
	Applications for initial treatment should be made where:						
	(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or						
	(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or						
	(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).						
	A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.						
	Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.						
	For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.						
	(b) Continuing treatment.						
	Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.						
	It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.						
	(2) Swapping therapy.						
	Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.						
	A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the						

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing. (3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements. For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. (4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.							
	<u>Authority required</u> Ankylosing spondylitis Treatment Phase: Continuing treatment – balance of supply Clinical criteria: Patient must have a documented history of active ankylosing spondylitis, AND Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Population criteria: Patient must be an adult. Treatment criteria: Must be treated by a rheumatologist. Note No increase in the maximum quantity or number of units may be authorised. Note No increase in the maximum number of repeats may be authorised. Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001							
9456Q	ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1	1	5	..	1774.71	37.70	Enbrel	PF
9086F	ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1	1	5	..	1774.71	37.70	Enbrel	PF
8779C	etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack	2	5	..	*1774.70	37.70	Enbrel	PF

ETANERCEPT

Authority required

Severe psoriatic arthritis

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)						
	Clinical criteria:						
	Patient must have severe active psoriatic arthritis,						
	AND						
	Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR						
	Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition,						
	AND						
	Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months,						
	AND						
	Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR						
	Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months,						
	AND						
	Patient must not receive more than 16 weeks of treatment under this restriction.						
	Population criteria:						
	Patient must be an adult.						
	Treatment criteria:						
	Must be treated by a rheumatologist; OR						
	Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.						
	For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.						
	Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.						
	Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.						
	The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:						
	an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and either						
	(a) an active joint count of at least 20 active (swollen and tender) joints; or						
	(b) at least 4 active joints from the following list of major joints:						
	(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or						
	(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).						
	If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.						
	The authority application must be made in writing and must include:						
	(1) a completed authority prescription form; and						
	(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and						
	(3) a signed patient acknowledgement.						
	Note						
	Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)						
	Note						
	The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.						
	Note						
	Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.						
	Note						
	No increase in the maximum quantity or number of units may be authorised.						
	Note						

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

No increase in the maximum number of repeats may be authorised.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

Clinical criteria:

Patient must have a documented history of severe active psoriatic arthritis,

AND

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle,

AND

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle,

AND

Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
- (iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - certolizumab pegol only.

For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	(2) Continuing treatment.						
	Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.						
	Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.						
	Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.						
	(3) Swapping therapy.						
	Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.						
	Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.						
	Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:						
	(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or						
	(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and						
	(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.						
	To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.						
	To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.						
	(4) Baseline measurements to determine response.						
	The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.						
	To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.						
	(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.						
	Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.						
	<u>Authority required</u>						
	Severe psoriatic arthritis						
	Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply						
	Clinical criteria:						
	Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR						
	Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 16 weeks treatment,						
	AND						
	The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.						
	Treatment criteria:						
	Must be treated by a rheumatologist; OR						
	Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.						
	<u>Note</u>						
	No increase in the maximum quantity or number of units may be authorised.						
	<u>Note</u>						
	No increase in the maximum number of repeats may be authorised.						
	<u>Note</u>						
	Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the						

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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	Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).							
	Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:							
	Department of Human Services							
	Prior Written Approval of Complex Drugs							
	Reply Paid 9826							
	GPO Box 9826							
	HOBART TAS 7001							
9457R	ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1	1	3	..	1774.71	37.70	Enbrel	PF
9087G	ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1	1	3	..	1774.71	37.70	Enbrel	PF
9035M	etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack	2	3	..	*1774.70	37.70	Enbrel	PF

ETANERCEPT

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active psoriatic arthritis,

AND

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle,

AND

Patient must demonstrate, at the time of application, an adequate response to treatment with this drug,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Note

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
- (iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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agent.

Grandfather patients - certolizumab pegol only.

For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
- (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment,

AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note

No increase in the maximum quantity or number of units may be authorised.

[illegible]

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

- (a) a total active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list of major joints:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note

Special Pricing Arrangements apply.

Note

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application. Rituximab patients: A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate. (b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients: A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. (2) Swapping therapy. Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled. Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent. A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug. Abatacept patients: Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation. In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment. To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period. To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing. (3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.						

Authority required

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	Severe active rheumatoid arthritis						
	Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months)						
	Clinical criteria:						
	Patient must have a documented history of severe active rheumatoid arthritis,						
	AND						
	Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy,						
	AND						
	Patient must not receive more than 16 weeks of treatment under this restriction.						
	Population criteria:						
	Patient must be aged 18 years or older.						
	Treatment criteria:						
	Must be treated by a rheumatologist; OR						
	Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.						
	For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.						
	The authority application must be made in writing and must include:						
	(a) a completed authority prescription form; and						
	(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.						
	Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.						
	Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.						
	Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.						
	Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.						
	If a patient fails to demonstrate a response to a treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.						
	A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD						
	An adequate response to treatment is defined as:						
	an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;						
	AND either of the following:						
	(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or						
	(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:						
	(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or						
	(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).						
	Note						
	Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).						
	Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au						
	Applications for authority to prescribe should be forwarded to:						
	Department of Human Services						
	Prior Written Approval of Complex Drugs						
	Reply Paid 9826						
	HOBART TAS 7001						
	Note						
	TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS						
	The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and						

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept). Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.						
	In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.						
	A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:						
	a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,						
	a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and						
	once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.						
	For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.						
	A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.						
	The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.						
	(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.						
	(a) Initial treatment.						
	Applications for initial treatment should be made where:						
	(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or						
	(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or						
	(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or						
	(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).						
	Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.						
	Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.						
	A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.						
	Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.						
	Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.						
	For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.						
	Abatacept patients:						
	Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.						
	Rituximab patients:						
	A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.						
	(b) Continuing treatment.						
	Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.						
	It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.						
	Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from						

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment,

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
Note								
Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).								
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:								
Department of Human Services								
Prior Written Approval of Complex Drugs								
Reply Paid 9826								
GPO Box 9826								
HOBART TAS 7001								
9459W	ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1	1	3	..	1774.71	37.70	Enbrel	PF
9089J	ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1	1	3	..	1774.71	37.70	Enbrel	PF
8637N	etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack	2	3	..	*1774.70	37.70	Enbrel	PF

ETANERCEPT

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis,

AND

Patient must have demonstrated an adequate response to treatment with this drug,

AND

Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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					Price for Max. Qty \$	Recordable Value for Safety Net \$	

treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	Department of Human Services	within 4 weeks.					
	Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.						
	For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.						
	Abatacept patients:						
	Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.						
	Rituximab patients:						
	A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.						
	(b) Continuing treatment.						
	Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.						
	It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.						
	Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.						
	Rituximab patients:						
	A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.						
	Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.						
	(2) Swapping therapy.						
	Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.						
	Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.						
	A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.						
	Abatacept patients:						
	Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.						
	In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.						
	To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.						
	PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.						
	To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.						
	(3) Baseline measurements to determine response.						
	The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.						
	To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of						

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.							
	Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.							
	Authority required							
	Severe active rheumatoid arthritis							
	Treatment Phase: Continuing Treatment – balance of supply							
	Clinical criteria:							
	Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment,							
	AND							
	The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.							
	Treatment criteria:							
	Must be treated by a rheumatologist; OR							
	Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.							
	Note							
	Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).							
	Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:							
	Department of Human Services							
	Prior Written Approval of Complex Drugs							
	Reply Paid 9826							
	GPO Box 9826							
	HOBART TAS 7001							
9460X	ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1	1	5	..	1774.71	37.70	Enbrel	PF
9090K	ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1	1	5	..	1774.71	37.70	Enbrel	PF
8638P	etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack	2	5	..	*1774.70	37.70	Enbrel	PF

ETANERCEPT

Authority required

Initial treatment [Initial 1, Whole body (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

- (a) have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and
- (b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
- (c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); and
- (d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:
 - (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or
 - (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or
 - (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or
 - (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

- (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]]; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

A maximum of 16 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised etanercept treatment

Authority required

Initial or re-Treatment [Initial 2, Whole body (Received prior biological agent under PBS)]

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised therapy with etanercept for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]]; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised etanercept treatment within this Treatment Cycle and who wish to re-commence etanercept treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised etanercept treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 16 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised etanercept treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

Cycle

Authority required

Initial treatment [Initial 1, Face, hand, foot (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and

(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot); and

(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:

(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or

(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or

(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or

(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

A maximum of 16 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised etanercept treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline

Authority required

Initial or re-Treatment [Initial 2, Face, hand, foot (Received prior biological agent under PBS)]

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised therapy with etanercept for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised etanercept treatment within this Treatment Cycle and who wish to re-commence etanercept treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised etanercept treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 16 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised etanercept treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab and ustekinumab.

From 1 March 2010, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept, infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 March 2010 is considered to be in their first Cycle as of 1 March 2010.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 March 2010, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2010.

Patients must be assessed for response to each course of continuing treatment according to the criteria included in the relevant continuing

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 March 2010.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or
- (iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept, infliximab or ustekinumab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

Patients who commenced treatment with adalimumab prior to 1 June 2009 or ustekinumab prior to 1 March 2010 access these interchangeability arrangements in the same way as patients who have not.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	of response to treatment for the purposes of all continuing treatment applications.							
	(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.							
	Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.							
	Note							
	No applications for increased maximum quantities and/or repeats will be authorised.							
	Note							
	Special Pricing Arrangements apply.							
9461Y	ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1	1	3	..	1774.71	37.70	Enbrel	PF
9091L	ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1	1	3	..	1774.71	37.70	Enbrel	PF
9037P	etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack	2	3	..	*1774.70	37.70	Enbrel	PF

ETANERCEPT

Authority required

Continuing treatment (Whole body)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

- (a) who have a documented history of severe chronic plaque psoriasis; and
- (b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with etanercept; and
- (c) who have demonstrated an adequate response to their most recent course of treatment with etanercept.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-biological treatment baseline value for this Treatment Cycle.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet along with the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with etanercept.

A maximum of 24 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised etanercept treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority required

Continuing treatment (Face, hand, foot)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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- (a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and
- (b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with etanercept; and
- (c) who have demonstrated an adequate response to treatment with etanercept.

An adequate response to etanercept treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
- (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

The most recent PASI assessment must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised etanercept treatment.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

Note

Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab and ustekinumab.

From 1 March 2010, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept, infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 March 2010 is considered to be in their first Cycle as of 1 March 2010.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once.

[illegible]

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score. To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications. (6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.							
	Note No applications for increased maximum quantities and/or repeats will be authorised.							
	Note Special Pricing Arrangements apply.							
9462B	ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1	1	5	..	1774.71	37.70	Enbrel	PF
9431J	ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1	1	5	..	1774.71	37.70	Enbrel	PF
9429G	etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack	2	5	..	*1774.70	37.70	Enbrel	PF

GOLIMUMAB

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have severe active rheumatoid arthritis,

AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months,

AND

Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times,

AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly,

AND

Patient must not receive more than 16 weeks of treatment under this restriction,

AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

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	Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab. If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and (3) a signed patient acknowledgement. Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased. Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response. Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes: (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose; (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;						

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for	Maximum Recordable Value for	Brand Name and Manufacturer
					Max. Qty \$	Safety Net \$	
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.							

Note

Special Pricing Arrangements apply.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months)

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis,

AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy,

AND

Patient must not receive more than 16 weeks of treatment under this restriction,

AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form and
- (b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

Special Pricing Arrangements apply.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

[illegible]

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.							
	Clinical criteria:							
	Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR							
	Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment,							
	AND							
	The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.							
	Treatment criteria:							
	Must be treated by a rheumatologist; OR							
	Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.							
	<u>Note</u>							
	Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).							
	Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:							
	Department of Human Services							
	Prior Written Approval of Complex Drugs							
	Reply Paid 9826							
	GPO Box 9826							
	HOBART TAS 7001							
3426H	golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe	1	3	..	1777.63	37.70	Simponi	JC
3427J	golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe	1	3	..	1777.63	37.70	Simponi	JC

GOLIMUMAB

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis,

AND

Patient must have demonstrated an adequate response to treatment with this drug,

AND

Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction,

AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with golimumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with golimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with golimumab.

If a patient fails to demonstrate a response to treatment with golimumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note

Special Pricing Arrangements apply.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alpha antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

Note

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialed.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment. To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period. To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing. (3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. <u>Authority required</u> Severe active rheumatoid arthritis Treatment Phase: Continuing Treatment – balance of supply Clinical criteria: Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Treatment criteria: Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. <u>Note</u> Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001							
3428K	golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe	1	5	..	1777.63	37.70	Simponi	JC
3429L	golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe	1	5	..	1777.63	37.70	Simponi	JC

GOLIMUMAB

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe active psoriatic arthritis,

AND

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, AND Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, AND Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, AND Patient must not receive more than 16 weeks of treatment under this restriction. Population criteria: Patient must be an adult. Treatment criteria: Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab. Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and either (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and (3) a signed patient acknowledgement. Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au) Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment. Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle. Note No increase in the maximum quantity or number of units may be authorised. Note No increase in the maximum number of repeats may be authorised. Authority required Severe psoriatic arthritis Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment) Clinical criteria:						

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	Patient must have a documented history of severe active psoriatic arthritis, AND Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, AND Patient must not receive more than 16 weeks of treatment under this restriction. Population criteria: Patient must be an adult. Treatment criteria: Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form. Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug. Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased. Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased. Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment. Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle. Note No increase in the maximum quantity or number of units may be authorised. Note No increase in the maximum number of repeats may be authorised. Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to:						

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
- (iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - certolizumab pegol only.

For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent. (3) Swapping therapy. Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not. Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing: (i) they have not received PBS-subsidised treatment with that particular biological agent previously; or (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialed it on the PBS; and (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle. To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing. (4) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints. (5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured. <u>Authority required</u> Severe psoriatic arthritis Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply <u>Clinical criteria:</u> Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 16 weeks treatment, <u>AND</u> The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. <u>Treatment criteria:</u> Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. <u>Note</u> No increase in the maximum quantity or number of units may be authorised. <u>Note</u> No increase in the maximum number of repeats may be authorised. <u>Note</u> Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826						

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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	GPO Box 9826							
	HOBART TAS 7001							
3430M	golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe	1	3	..	1777.63	37.70	Simponi	JC
3431N	golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe	1	3	..	1777.63	37.70	Simponi	JC

GOLIMUMAB

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active psoriatic arthritis,

AND

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle,

AND

Patient must demonstrate, at the time of application, an adequate response to treatment with this drug,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Note

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

[illegible]

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

[illegible]

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Prior Written Approval of Complex Drugs							
	Reply Paid 9826							
	GPO Box 9826							
	HOBART TAS 7001							
3432P	golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe	1	5	..	1777.63	37.70	Simponi	JC
3433Q	golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe	1	5	..	1777.63	37.70	Simponi	JC

GOLIMUMAB

Authority required

Active ankylosing spondylitis

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis,

AND

Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab or infliximab in this treatment cycle,

AND

Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender,

AND

Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) a signed patient acknowledgment.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle. <u>Note</u> Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au <u>Note</u> For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au <u>Note</u> No increase in the maximum quantity or number of units may be authorised. <u>Note</u> No increase in the maximum number of repeats may be authorised. <u>Authority required</u> Ankylosing spondylitis Treatment Phase: Initial 2 (change or recommencement for all patients) Clinical criteria: Patient must have a documented history of active ankylosing spondylitis, AND Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, AND Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, AND Patient must be eligible to receive further bDMARD therapy. Population criteria: Patient must be an adult. Treatment criteria: Must be treated by a rheumatologist. Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment. Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form. A maximum of 16 weeks of treatment with this drug will be approved under this criterion. Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle. <u>Note</u> No increase in the maximum quantity or number of units may be authorised. <u>Note</u> No increase in the maximum number of repeats may be authorised. <u>Note</u> Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services						

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.

Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	prescription or remaining repeats for the bDMARD the patient is ceasing.							
	(3) Baseline measurements to determine response.							
	The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.							
	For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.							
	To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.							
	(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.							
	A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.							
	Authority required							
	Ankylosing spondylitis							
	Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply							
	Clinical criteria:							
	Patient must have active, or a documented history of active, ankylosing spondylitis,							
	AND							
	Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 16 weeks treatment; OR							
	Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 16 weeks treatment,							
	AND							
	The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.							
	Population criteria:							
	Patient must be an adult.							
	Treatment criteria:							
	Must be treated by a rheumatologist.							
	Note							
	No increase in the maximum quantity or number of units may be authorised.							
	Note							
	No increase in the maximum number of repeats may be authorised.							
	Note							
	Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).							
	Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:							
	Department of Human Services							
	Prior Written Approval of Complex Drugs							
	Reply Paid 9826							
	GPO Box 9826							
	HOBART TAS 7001							
3434R	golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe	1	3	..	1777.63	37.70	Simponi	JC
3435T	golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe	1	3	..	1777.63	37.70	Simponi	JC

GOLIMUMAB

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of active ankylosing spondylitis,

AND

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, AND Patient must have demonstrated an adequate response to treatment with this drug. Population criteria: Patient must be an adult. Treatment criteria: Must be treated by a rheumatologist. An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form. All measurements provided must be no more than 1 month old at the time of application. A maximum of 24 weeks of treatment with this drug will be authorised under this criterion. All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment. Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle. Note No increase in the maximum quantity or number of units may be authorised. Note No increase in the maximum number of repeats may be authorised. Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 Note TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis. Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only. A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time. From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy. A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.						

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle. A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle. A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle. There is no limit to the number of treatment cycles a patient may undertake in their lifetime. (1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010. (a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or (ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2). A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course. (b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. (2) Swapping therapy. Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements. A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing. (3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements. For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. (4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.						

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment – balance of supply

Clinical criteria:

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Patient must have a documented history of active ankylosing spondylitis, AND Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Population criteria: Patient must be an adult. Treatment criteria: Must be treated by a rheumatologist. Note No increase in the maximum quantity or number of units may be authorised. Note No increase in the maximum number of repeats may be authorised. Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001							
3436W	golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe	1	5	..	1777.63	37.70	Simponi	JC
3437X	golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe	1	5	..	1777.63	37.70	Simponi	JC

Interleukin inhibitors

USTEKINUMAB

Authority required

Initial treatment [Initial 1, Whole body (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

- (a) have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and
- (b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
- (c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); and
- (d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:
 - (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or
 - (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or
 - (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or
 - (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

- (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 1 month old at the time of application.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
 - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
 - (iii) the signed patient and prescriber acknowledgements.

A maximum of 28 weeks of treatment with ustekinumab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 28 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with ustekinumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised ustekinumab treatment

Authority required

Initial or re-Treatment [Initial 2, Whole body (Received prior biological agent under PBS)]

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

- (a) have a documented history of severe chronic plaque psoriasis; and
- (b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
- (c) have not failed PBS-subsidised therapy with ustekinumab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
 - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised ustekinumab treatment within this Treatment Cycle and who wish to re-commence ustekinumab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised ustekinumab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 28 weeks of treatment with ustekinumab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 28 weeks.

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with ustekinumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised ustekinumab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

Authority required

Initial treatment [Initial 1, Face, hand, foot (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and

(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot); and

(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:

(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or

(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or

(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or

(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

A maximum of 28 weeks of treatment with ustekinumab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 28 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with ustekinumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised ustekinumab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline

Authority required

Initial or re-Treatment [Initial 2, Face, hand, foot (Received prior biological agent under PBS)]

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

- (a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and
- (b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
- (c) have not failed PBS-subsidised therapy with ustekinumab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
- (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
- (ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised ustekinumab treatment within this Treatment Cycle and who wish to re-commence ustekinumab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised ustekinumab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 28 weeks of treatment with ustekinumab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 28 weeks.

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with ustekinumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised ustekinumab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

Any queries concerning the arrangements to prescribe ustekinumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe ustekinumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab and ustekinumab.

From 1 March 2010, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept, infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 March 2010 is considered to be in their first Cycle as of 1 March 2010.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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	wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 March 2010, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2010.						
	Patients must be assessed for response to each course of continuing treatment according to the criteria included in the relevant continuing treatment restriction.						
	Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.						
	Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.						
	Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.						
	There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.						
	How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 March 2010.						
	There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.						
	(1) Application for approval for initial treatment.						
	Applications for a course of initial treatment should be made in the following situations:						
	(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or						
	(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or						
	(iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).						
	All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.						
	(2) Assessment of response to initial treatment.						
	When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.						
	The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.						
	(3) Application for continuing treatment.						
	Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.						
	For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept, infliximab or ustekinumab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.						
	Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.						
	(4) Swapping therapy.						
	Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.						
	Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.						
	Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.						
	Patients who commenced treatment with adalimumab prior to 1 June 2009 or ustekinumab prior to 1 March 2010 access these interchangeability arrangements in the same way as patients who have not.						
	To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.						
	To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.						
	(5) Baseline measurements to determine response.						
	Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted						

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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	with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score. To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications. (6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application. Note No applications for increased repeats will be authorised. Note Special Pricing Arrangements apply.						
9304Q	ustekinumab 45 mg/0.5 mL injection, 1 x 0.5 mL vial	1	2	..	4601.76	37.70	Stelara JC

USTEKINUMAB

Authority required

Continuing treatment (Whole body)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

- (a) who have a documented history of severe chronic plaque psoriasis; and
- (b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with ustekinumab; and
- (c) who have demonstrated an adequate response to their most recent course of treatment with ustekinumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-biological treatment baseline value for this Treatment Cycle.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with ustekinumab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet along with the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with ustekinumab.

A maximum of 24 weeks of treatment with ustekinumab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.

Where fewer than 1 repeat is requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with ustekinumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised ustekinumab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority required

Continuing treatment (Face, hand, foot)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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- (a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and
- (b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with ustekinumab; and
- (c) who have demonstrated an adequate response to treatment with ustekinumab.

An adequate response to ustekinumab treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with ustekinumab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
- (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

The most recent PASI assessment must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with ustekinumab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.

Where fewer than 1 repeat is requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with ustekinumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised ustekinumab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

Any queries concerning the arrangements to prescribe ustekinumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe ustekinumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab and ustekinumab.

From 1 March 2010, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept, infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 March 2010 is considered to be in their first Cycle as of 1 March 2010.

[illegible]

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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	prescription or remaining repeats for the agent being ceased.							
	(5) Baseline measurements to determine response.							
	Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.							
	To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.							
	(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.							
	Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.							
	Note							
	No applications for increased repeats will be authorised.							
	Note							
	Special Pricing Arrangements apply.							

9305R	ustekinumab 45 mg/0.5 mL injection, 1 x 0.5 mL vial	1	1	..	4601.76	37.70	Stelara	JC

Calcineurin inhibitors

CYCLOSPORIN

Caution

Careful monitoring of patients is mandatory.

8657P	cyclosporin 10 mg capsule, 60	2	3	..	*94.76	37.70	Neoral 10	NV
8660T	cyclosporin 100 mg capsule, 30	2	3	..	*374.78	37.70	^a Cyclosporin Sandoz	SZ
							^a Neoral 100	NV
8661W	cyclosporin 100 mg/mL oral liquid, 50 mL	2	3	..	*713.00	37.70	Neoral	NV
8658Q	cyclosporin 25 mg capsule, 30	2	3	..	*97.58	37.70	^a Cyclosporin Sandoz	SZ
							^a Neoral 25	NV
8659R	cyclosporin 50 mg capsule, 30	2	3	..	*195.72	37.70	^a Cyclosporin Sandoz	SZ
							^a Neoral 50	NV

TACROLIMUS

Caution

Careful monitoring of patients is mandatory.

8647D	tacrolimus 1 mg capsule, 100	1	3	..	340.63	37.70	^a Pharmacor Tacrolimus 1	CR
							^a Prograf	LL
							^a Tacrolimus Sandoz	SZ
5300Y	tacrolimus 1 mg capsule: modified release, 60 capsules	1	3	..	214.27	37.70	Prograf XL	LL
8648E	tacrolimus 5 mg capsule, 50	1	3	..	827.61	37.70	^a Pharmacor Tacrolimus 5	CR
							^a Prograf	LL
							^a Tacrolimus Sandoz	SZ
5451X	tacrolimus 5 mg capsule: modified release, 30 capsules	1	3	..	499.53	37.70	Prograf XL	LL
8646C	tacrolimus 500 microgram capsule, 100	1	3	..	180.49	37.70	^a Pharmacor Tacrolimus 0.5	CR
							^a Prograf	LL
							^a Tacrolimus Sandoz	SZ
5299X	tacrolimus 500 microgram capsule: modified release, 30 capsules	1	3	..	58.88	37.70	Prograf XL	LL

Other immunosuppressants

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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AZATHIOPRINE							
Note							
Shared Care Model:							
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
2688L NP	azathioprine 25 mg tablet, 100	1	5	..	26.22	27.37	^a APO-Azathioprine TX
							^a Azathioprine GH GQ
							^a Azathioprine Sandoz SZ
							^a Imuran AS
2687K NP	azathioprine 50 mg tablet, 100	1	5	..	39.88	37.70	^a APO-Azathioprine TX
							^a Azamun GN
							^a Azapin QA
							^a Azathioprine AN EA
							^a Azathioprine GH GQ
							^a Azathioprine Sandoz SZ
							^a GenRx Azathioprine GX
							^a Imazan ER
							^a Imuran AS
							^a Thioprine AF
METHOTREXATE							
2272N	methotrexate 10 mg tablet, 15	1	3	..	20.68	21.83	Methoblastin PF
1622J	methotrexate 2.5 mg tablet, 30	1	5	..	13.46	14.61	^a Hospira Pty Limited HH
							^a Methoblastin PF
METHOTREXATE							
Restricted benefit							
For patients requiring doses greater than 20 mg per week							
1623K	methotrexate 10 mg tablet, 50	1	2	..	51.58	37.70	Methoblastin PF

MUSCULO-SKELETAL SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

MUSCULO-SKELETAL SYSTEM

ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS

ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS

Acetic acid derivatives and related substances

DICLOFENAC

1302M NP,MW	diclofenac sodium 100 mg suppository, 20	2	3	..	*25.26	26.41	Voltaren 100	NV
5079H DP	diclofenac sodium 100 mg suppository, 20	2	..	..	*25.26	26.41	Voltaren 100	NV

DICLOFENAC

Restricted benefit

Chronic arthropathies (including osteoarthritis) with an inflammatory component

Restricted benefit

Bone pain due to malignant disease

1299J NP	diclofenac sodium 25 mg tablet: enteric, 50 tablets	2	3	..	*10.62	11.77	^a APO-Diclofenac	TX
							^a Chem mart Diclofenac	CH
							^a Clonac 25	QA
							^a Diclofenac AN	EA
							^a Diclofenac-GA	GN
							^a Diclofenac Sandoz	SZ
							^a Fenac 25	AF
							^a Terry White Chemists Diclofenac	TW
				^B 1.44	*12.06	11.77	^a Voltaren 25	NV
5076E DP	diclofenac sodium 25 mg tablet: enteric, 50 tablets	2	..	..	*10.62	11.77	^a APO-Diclofenac	TX
							^a Chem mart Diclofenac	CH
							^a Clonac 25	QA
							^a Diclofenac AN	EA
							^a Diclofenac-GA	GN
							^a Diclofenac Sandoz	SZ
							^a Fenac 25	AF
							^a Terry White Chemists Diclofenac	TW
				^B 1.44	*12.06	11.77	^a Voltaren 25	NV
1300K NP	diclofenac sodium 50 mg tablet: enteric, 50 tablets	1	3	..	9.44	10.59	^a APO-Diclofenac	TX
							^a Chem mart Diclofenac	CH
							^a Clonac 50	QA
							^a Diclofenac AN	EA
							^a Diclofenac-GA	GN
							^a Diclofenac Sandoz	SZ
							^a Fenac	AF
							^a Terry White Chemists Diclofenac	TW
				^B 1.43	10.87	10.59	^a Voltaren 50	NV
5077F DP	diclofenac sodium 50 mg tablet: enteric, 50 tablets	1	..	..	9.44	10.59	^a APO-Diclofenac	TX
							^a Chem mart Diclofenac	CH
							^a Clonac 50	QA
							^a Diclofenac AN	EA
							^a Diclofenac-GA	GN
							^a Diclofenac Sandoz	SZ
							^a Fenac	AF
							^a Terry White Chemists Diclofenac	TW
				^B 1.43	10.87	10.59	^a Voltaren 50	NV

INDOMETHACIN

MUSCULO-SKELETAL SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
2757D NP	indomethacin 100 mg suppository, 20	2	3	..	*22.84	23.99	Indocid	AS
5128X DP	indomethacin 100 mg suppository, 20	2	..	..	*22.84	23.99	Indocid	AS

INDOMETHACIN

Restricted benefit

Chronic arthropathies (including osteoarthritis) with an inflammatory component

Restricted benefit

Bone pain due to malignant disease

2454E NP	indomethacin 25 mg capsule, 50	2	3	..	*13.20	14.35	^a Arthrexin	AF
				^B 4.64	*17.84	14.35	^a Indocid	AS
5126T DP	indomethacin 25 mg capsule, 50	2	..	..	*13.20	14.35	^a Arthrexin	AF
				^B 4.64	*17.84	14.35	^a Indocid	AS

Oxicams

MELOXICAM

Restricted benefit

Symptomatic treatment of osteoarthritis

Restricted benefit

Symptomatic treatment of rheumatoid arthritis

Note

The use of meloxicam for the treatment of the following conditions is not subsidised through the PBS:

- (a) acute pain;
- (b) soft tissue injury;
- (c) arthrosis without an inflammatory component.

Note

Pharmaceutical benefits that have the form meloxicam tablet 15 mg and pharmaceutical benefits that have the form meloxicam capsule 15 mg are equivalent for the purposes of substitution.

8888T NP	meloxicam 15 mg capsule, 30	1	3	..	13.35	14.50	^a APO-Meloxicam	TX
							^a Chem mart Meloxicam	CH
							^a Melox 15	GN
							^a Movalis 15	QA
							^a Terry White Chemists Meloxicam	TW
				^B 2.08	15.43	14.50	^a Mobic	BY
8562P NP	meloxicam 15 mg tablet, 30	1	3	..	13.35	14.50	^a APO-Meloxicam	TX
							^a Chem mart Meloxicam 15 mg	CH
							^a GenRx Meloxicam	GX
							^a Meloxiauro 15	DO
							^a Meloxibell	GQ
							^a Meloxicam AN	EA
							^a Meloxicam-GA	GN
							^a Meloxicam Ranbaxy	RA
							^a Meloxicam Sandoz	SZ
							^a Movalis 15	QA
							^a Moxicam 15	AF
							^a Pharmacor Meloxicam 15	CR
							^a Terry White Chemists Meloxicam 15 mg	TW
				^B 2.08	15.43	14.50	^a Mobic	BY

MELOXICAM

Restricted benefit

Symptomatic treatment of osteoarthritis

Restricted benefit

Symptomatic treatment of rheumatoid arthritis

MUSCULO-SKELETAL SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
Note The use of meloxicam for the treatment of the following conditions is not subsidised through the PBS: (a) acute pain; (b) soft tissue injury; (c) arthrosis without an inflammatory component.							
Note Pharmaceutical benefits that have the form meloxicam tablet 7.5 mg and pharmaceutical benefits that have the form meloxicam capsule 7.5 mg are equivalent for the purposes of substitution.							
8887R NP	meloxicam 7.5 mg capsule, 30	1	3	..	11.27	12.42	a APO-Meloxicam TX a Chem mart Meloxicam CH a Melox 7.5 GN a Movalis 7.5 QA a Terry White Chemists Meloxicam TW
8561N NP	meloxicam 7.5 mg tablet, 30	1	3	^B 2.09 ..	13.36 11.27	12.42 12.42	a Mobic BY a APO-Meloxicam TX a Chem mart Meloxicam 7.5 mg CH a GenRx Meloxicam GX a Meloxiauro 7.5 DO a Meloxibell GQ a Meloxicam AN EA a Meloxicam-GA GN a Meloxicam Ranbaxy RA a Meloxicam Sandoz SZ a Movalis 7.5 QA a Moxicam 7.5 AF a Pharmacor Meloxicam 7.5 CR a Terry White Chemists Meloxicam 7.5 mg TW ^B 2.09 13.36 12.42 a Mobic BY
PIROXICAM Restricted benefit Chronic arthropathies (including osteoarthritis) with an inflammatory component							
1897W NP	piroxicam 10 mg capsule, 50	1	3	..	12.54	13.69	a Chem mart Piroxicam CH a GenRx Piroxicam GX a Mobilis 10 AF a Terry White Chemists Piroxicam TW
5203W DP	piroxicam 10 mg capsule, 50	1	..	^B 3.08 ..	15.62 12.54	13.69 13.69	a Feldene PF a Chem mart Piroxicam CH a GenRx Piroxicam GX a Mobilis 10 AF a Terry White Chemists Piroxicam TW
1895R NP	piroxicam 10 mg tablet: dispersible, 50	1	3	^B 3.08 ..	15.62 12.54	13.69 13.69	a Feldene PF Mobilis D-10 AF
5201R DP	piroxicam 10 mg tablet: dispersible, 50	1	..	..	12.54	13.69	Mobilis D-10 AF
1898X NP	piroxicam 20 mg capsule, 25	1	3	..	12.26	13.41	a Chem mart Piroxicam CH a GenRx Piroxicam GX a Mobilis 20 AF a Terry White Chemists Piroxicam TW
5204X DP	piroxicam 20 mg capsule, 25	1	..	^B 2.86 ..	15.12 12.26	13.41 13.41	a Feldene PF a Chem mart Piroxicam CH

MUSCULO-SKELETAL SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							^a GenRx Piroxicam	GX
							^a Mobilis 20	AF
							^a Terry White Chemists Piroxicam	TW
				^B 2.86	15.12	13.41	^a Feldene	PF
1896T NP	piroxicam 20 mg tablet: dispersible, 25	1	3	..	12.26	13.41	^a Mobilis D-20	AF
				^B 3.86	16.12	13.41	^a Feldene-D	PF
5202T DP	piroxicam 20 mg tablet: dispersible, 25	1	..	..	12.26	13.41	^a Mobilis D-20	AF
				^B 3.86	16.12	13.41	^a Feldene-D	PF
Propionic acid derivatives								
IBUPROFEN								
Restricted benefit								
Chronic arthropathies (including osteoarthritis) with an inflammatory component								
Restricted benefit								
Bone pain due to malignant disease								
3190X NP	ibuprofen 400 mg tablet, 30	3	3	..	*15.07	16.22	Brufen	GO
5123P DP	ibuprofen 400 mg tablet, 30	3	..	..	*15.07	16.22	Brufen	GO
IBUPROFEN								
3192B NP,MW	ibuprofen 400 mg tablet, 30	1	..	..	9.53	10.68	Brufen	GO
5124Q DP	ibuprofen 400 mg tablet, 30	1	..	..	9.53	10.68	Brufen	GO
KETOPROFEN								
1588N NP	ketoprofen 100 mg suppository, 20	2	3	..	*25.64	26.79	Orudis	SW
5139L DP	ketoprofen 100 mg suppository, 20	2	..	..	*25.64	26.79	Orudis	SW
KETOPROFEN								
Restricted benefit								
Chronic arthropathies (including osteoarthritis) with an inflammatory component								
1590Q NP	ketoprofen 200 mg capsule: modified release, 28 capsules	1	3	..	19.44	20.59	^a Oruvail SR	AV
				^B 2.21	21.65	20.59	^a Orudis SR 200	SW
5136H DP	ketoprofen 200 mg capsule: modified release, 28 capsules	1	..	..	19.44	20.59	^a Oruvail SR	AV
				^B 2.21	21.65	20.59	^a Orudis SR 200	SW
NAPROXEN								
Restricted benefit								
Chronic arthropathies (including osteoarthritis) with an inflammatory component								
Restricted benefit								
Bone pain due to malignant disease								
1615B NP	naproxen 1 g tablet: modified release, 28	1	3	..	14.30	15.45	^a Proxen SR 1000	MD
				^B 1.29	15.59	15.45	^a Naprosyn SR1000	RO
5179N DP	naproxen 1 g tablet: modified release, 28	1	..	..	14.30	15.45	^a Proxen SR 1000	MD
				^B 1.29	15.59	15.45	^a Naprosyn SR1000	RO
1674D NP	naproxen 250 mg tablet, 50	2	3	..	*13.68	14.83	^a Inza 250	AF
				^B 2.24	*15.92	14.83	^a Naprosyn	RO
5176K DP	naproxen 250 mg tablet, 50	2	..	..	*13.68	14.83	^a Inza 250	AF
				^B 2.24	*15.92	14.83	^a Naprosyn	RO
1659H NP	naproxen 500 mg tablet, 50	1	3	..	12.94	14.09	^a Inza 500	AF
				^B 1.28	14.22	14.09	^a Naprosyn	RO
5177L	naproxen 500 mg tablet, 50	1	..	..	12.94	14.09	^a Inza 500	AF

MUSCULO-SKELETAL SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
DP								
1614Y NP	naproxen 750 mg tablet: modified release, 28 tablets	1	3	^B 1.28 ..	14.22 12.42	14.09 13.57	^a Naprosyn ^a Proxen SR 750	RO MD
5178M DP	naproxen 750 mg tablet: modified release, 28 tablets	1	..	^B 1.22 ..	13.64 12.42	13.57 13.57	^a Naprosyn SR750 ^a Proxen SR 750	RO MD
				^B 1.22	13.64	13.57	^a Naprosyn SR750	RO

NAPROXEN

Authority required (STREAMLINED)

4159

Chronic arthropathies (including osteoarthritis)

Clinical criteria:

The condition must have an inflammatory component,

AND

Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent.

Authority required (STREAMLINED)

4124

Bone pain

Clinical criteria:

The condition must be due to malignant disease,

AND

Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent.

1658G NP	naproxen 125 mg/5 mL oral liquid, 474 mL	1	3	..	127.96	37.70	Phebra Naproxen Suspension	PL

NAPROXEN

Restricted benefit

Chronic arthropathies (including osteoarthritis) with an inflammatory component

Restricted benefit

Bone pain due to malignant disease

Note

Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

1795L NP	naproxen sodium 550 mg tablet, 50	1	3	..	13.11	14.26	^a Crysanal	MD
				^B 2.17	15.28	14.26	^a Anaprox 550	RO
5186Y DP	naproxen sodium 550 mg tablet, 50	1	..	..	13.11	14.26	^a Crysanal	MD
				^B 2.17	15.28	14.26	^a Anaprox 550	RO

Fenamates

MEFENAMIC ACID

Restricted benefit

Dysmenorrhoea

Restricted benefit

Menorrhagia

1824B NP	mefenamic acid 250 mg capsule, 50	1	2	..	18.50	19.65	Ponstan	PF

Coxibs

CELECOXIB

Restricted benefit

Symptomatic treatment of osteoarthritis

Restricted benefit

Symptomatic treatment of rheumatoid arthritis

Note

The use of celecoxib for the treatment of the following conditions is not subsidised through the PBS:

- (a) acute pain;
- (b) soft tissue injury;

MUSCULO-SKELETAL SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	(c) arthrosis without an inflammatory component.							
8439E NP	celecoxib 100 mg capsule, 60	1	3	..	28.51	29.66	a APO-Celecoxib	TX
							a Blooms the Chemist Celecoxib	IB
							a Celaxib	AF
							a Celebrex	PF
							a Celecoxib Actavis	GN
							a Celecoxib AN	EA
							a Celecoxib GH	GQ
							a Celecoxib RBX	RA
							a Celecoxib Sandoz	SZ
							a Celexi	QA
							a Chem mart Celecoxib	CH
							a Kudeq	FZ
							a Terry White Chemists Celecoxib	TW
8440F NP	celecoxib 200 mg capsule, 30	1	3	..	28.51	29.66	a APO-Celecoxib	TX
							a Blooms the Chemist Celecoxib	IB
							a Celaxib	AF
							a Celebrex	PF
							a Celecoxib Actavis	GN
							a Celecoxib AN	EA
							a Celecoxib GH	GQ
							a Celecoxib RBX	RA
							a Celecoxib Sandoz	SZ
							a Celexi	QA
							a Chem mart Celecoxib	CH
							a Kudeq	FZ
							a Terry White Chemists Celecoxib	TW

SPECIFIC ANTIRHEUMATIC AGENTS

Quinolines

HYDROXYCHLOROQUINE

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1512N NP	hydroxychloroquine sulfate 200 mg tablet, 100	1	1	..	30.24	31.39	a APO-Hydroxychloroquine	TX
							a Chem mart Hydroxychloroquine	CH
							a Hydroxychloroquine Actavis	GN
							a Plaquenil	SW
							a Terry White Chemists Hydroxychloroquine	TW

Gold preparations

AURANOFIN

Caution

Regular blood and urine checks are essential.

2022K NP	AURANOFIN Capsule 3 mg, 60	1	5	..	779.33	37.70	Ridaura	GH

AURANOFIN

Caution

Regular blood and urine checks are essential.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised

MUSCULO-SKELETAL SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
1095P NP	auranofin 3 mg tablet, 60	1	5	..	63.89	37.70	Ridaura	GH

AUROTHIOMALATE SODIUM

Caution

Regular blood and urine checks are essential.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2016D NP	aurothiomalate sodium 10 mg/0.5 mL injection, 10 x 0.5 mL ampoules	1	..	..	83.64	37.70	Myocrisin	SW
2017E NP	aurothiomalate sodium 20 mg/0.5 mL injection, 10 x 0.5 mL ampoules	1	1	..	125.03	37.70	Myocrisin	SW
2018F NP	aurothiomalate sodium 50 mg/0.5 mL injection, 10 x 0.5 mL ampoules	1	1	..	152.81	37.70	Myocrisin	SW

Penicillamine and similar agents

PENICILLAMINE

Caution

Regular blood and urine checks are essential.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2721F NP	penicillamine 125 mg tablet, 100	1	1	..	31.97	33.12	D-Penamine	AL
2838J NP	penicillamine 250 mg tablet, 100	1	1	..	53.63	37.70	D-Penamine	AL

MUSCLE RELAXANTS

MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS

Other centrally acting agents

BACLOFEN

2729P NP	baclofen 10 mg tablet, 100	1	5	..	19.59	20.74	^a Chem mart Baclofen	CH
							^a Clofen 10	AF
							^a GenRx Baclofen	GX
							^a Lioresal 10	NV
							^a Stelax 10	QA
							^a Terry White Chemists Baclofen	TW
2730Q NP	baclofen 25 mg tablet, 100	1	5	..	34.81	35.96	^a Chem mart Baclofen	CH
							^a Clofen 25	AF
							^a GenRx Baclofen	GX
							^a Lioresal 25	NV
							^a Stelax 25	QA
							^a Terry White Chemists Baclofen	TW

MUSCLE RELAXANTS, DIRECTLY ACTING AGENTS

Dantrolene and derivatives

DANTROLENE

Restricted benefit

Treatment of chronic spasticity

1779P NP	dantrolene sodium 25 mg capsule, 100	1	2	..	81.53	37.70	Dantrium	PF
1780Q NP	dantrolene sodium 50 mg capsule, 100	1	2	..	82.15	37.70	Dantrium	PF

MUSCULO-SKELETAL SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

ANTIGOUT PREPARATIONS

ANTIGOUT PREPARATIONS

Preparations inhibiting uric acid production

ALLOPURINOL

Note

The dose should be adjusted in accordance with renal function.

Note

For item codes 2600W and 1557Y, pharmaceutical benefits that have the form tablet 100 mg are equivalent for the purposes of substitution.

1557Y NP	allopurinol 100 mg tablet, 100	2	2	..	*11.32	12.47	^a	Progout 100	AF
2600W NP	allopurinol 100 mg tablet, 200	1	2	..	11.31	12.46	^a	Allopurinol Sandoz	SZ
							^a	Allosig	FM
							^a	APO-Allopurinol	TX
							^a	Chem mart Allopurinol	CH
							^a	GenRx Allopurinol	GX
							^a	Terry White Chemists Allopurinol	TW
				^B 3.99	15.30	12.46	^a	Zyloprim	QA

ALLOPURINOL

Note

The dose should be adjusted in accordance with renal function.

2604C NP	allopurinol 300 mg tablet, 60	1	2	..	9.43	10.58	^a	Allopurinol Sandoz	SZ
							^a	Allosig	FM
							^a	APO-Allopurinol	TX
							^a	Chem mart Allopurinol	CH
							^a	GenRx Allopurinol	GX
							^a	Progout 300	AF
							^a	Terry White Chemists Allopurinol	TW
				^B 4.00	13.43	10.58	^a	Zyloprim	QA

Preparations increasing uric acid excretion

PROBENECID

1940D NP	probenecid 500 mg tablet, 100	1	5	..	76.03	37.70		Pro-Cid	PL

Preparations with no effect on uric acid metabolism

COLCHICINE

3410L NP	colchicine 500 microgram tablet, 30	1	5	..	11.34	12.49	^a	Lengout	LN
				^B 3.33	14.67	12.49	^a	Colgout	AS

DRUGS FOR TREATMENT OF BONE DISEASES

DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

Bisphosphonates

ALENDRONATE

Restricted benefit

Corticosteroid-induced osteoporosis

Clinical criteria:

Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy,

AND

Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less,

AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD

MUSCULO-SKELETAL SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

measurement must be documented in the patient's medical records when treatment is initiated.

Note

Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

Restricted benefit

Osteoporosis

Clinical criteria:

Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less,

AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

Population criteria:

Patient must be aged 70 years or older.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Note

Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

Restricted benefit

Established osteoporosis

Clinical criteria:

Patient must have fracture due to minimal trauma,

AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Note

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

8511Y NP	alendronate 70 mg tablet, 4	1	5	..	14.01	15.16	^a	Alendrobell 70mg	GQ
							^a	Alendronate AN	EA
							^a	Alendronate-GA	GN
							^a	Alendronate Sandoz	SZ
							^a	Alendro Once Weekly	QA
							^a	APO-Alendronate	TX
							^a	Chem mart	CH
							^a	Alendronate 70mg	
							^a	Densate 70	DO
							^a	Fonat	AL
							^a	Ossmax 70mg	RA
							^a	Terry White Chemists	TW
								Alendronate 70mg	

CLODRONATE

Restricted benefit

Maintenance treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy

Restricted benefit

Multiple myeloma

Restricted benefit

Bone metastases from breast cancer

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been

MUSCULO-SKELETAL SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
8132B NP	clodronate sodium 400 mg capsule, 100	1	2	..	334.42	37.70	Bonefos	BN
8265B NP	clodronate sodium 800 mg tablet, 60	1	2	..	391.78	37.70	Bonefos 800 mg	BN

IBANDRONIC ACID

Restricted benefit

Bone metastases from breast cancer

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

9357L NP	ibandronic acid 50 mg tablet, 28	1	2	..	342.68	37.70	Bondronat	RO

PAMIDRONATE DISODIUM

Restricted benefit

Symptomatic Paget disease of bone

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8461H NP	pamidronate disodium 15 mg/5 mL injection, 1 x 5 mL vial	4	..	..	*87.96	37.70	Pamisol	HH
8463K NP	pamidronate disodium 60 mg/10 mL injection, 1 x 10 mL vial	1	..	..	87.95	37.70	Pamisol	HH

PAMIDRONATE DISODIUM

Restricted benefit

Symptomatic Paget disease of bone

Note

Pharmaceutical benefits that have the form disodium pamidronate powder for I.V. infusion 30 mg (after reconstitution) and pharmaceutical benefits that have the form disodium pamidronate concentrated injection 30 mg are equivalent for the purposes of substitution.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8209C NP	pamidronate disodium 30 mg injection [2 x 30 mg vials] (& inert substance diluent [2 x 10 mL ampoules], 1 pack	1	..	..	87.96	37.70	^a Aredia 30 mg	NV
8462J NP	pamidronate disodium 30 mg/10 mL injection, 1 x 10 mL vial	2	..	..	*87.96	37.70	^a Pamisol	HH

RISEDRONATE

Restricted benefit

Corticosteroid-induced osteoporosis

Clinical criteria:

Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy,

AND

Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less,

AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Note

Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

Restricted benefit

MUSCULO-SKELETAL SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
Osteoporosis Clinical criteria: Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. Population criteria: Patient must be aged 70 years or older. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated. Note Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid. Restricted benefit Established osteoporosis Clinical criteria: Patient must have fracture due to minimal trauma, AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body. Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.								
8972F NP	RISEDRONATE SODIUM Tablet 35 mg (enteric coated), 4	1	5	..	42.11	37.70	Actonel EC	UA
9391G NP	risedronate sodium 150 mg tablet, 1	1	5	..	44.69	37.70	^a Acris Once-a-Month	AF
							^a Actonel Once-a-Month	UA
							^a APO-Risedronate	TX
							^a Chem mart Risedronate	CH
							^a Terry White Chemists Risedronate	TW
8621R NP	risedronate sodium 35 mg tablet, 4	1	5	..	42.11	37.70	^a Acris Once-a-Week	AF
							^a APO-Risedronate	TX
							^a Risedronate AN	EA
							^a Risedronate-GA	GN
							^a Risedronate Sandoz	SZ
							^a Risedro once a week	QA
8481J NP	risedronate sodium 5 mg tablet, 28	1	5	..	42.11	37.70	Actonel	UA
RISEDRONATE Restricted benefit Symptomatic Paget disease of bone Note Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8482K NP	risedronate sodium 30 mg tablet, 28	1	1	..	235.41	37.70	Actonel	UA

TILUDRONATE

Restricted benefit

Symptomatic Paget disease of bone

MUSCULO-SKELETAL SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Note Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
8267D NP	tiludronate 200 mg tablet, 56	1	2	..	304.96	37.70	Skelid	SW
	ZOLEDRONIC ACID Authority required (STREAMLINED) 4100 Corticosteroid-induced osteoporosis Clinical criteria: Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, AND Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, AND Patient must not receive more than one PBS-subsidised treatment per year. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated. Authority required (STREAMLINED) 4149 Osteoporosis Clinical criteria: Patient must have a Bone Mineral Density (BMD) T-score of -3.0 or less, AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, AND Patient must not receive more than one PBS-subsidised treatment per year. Population criteria: Patient must be aged 70 years or older. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated. Authority required (STREAMLINED) 4157 Established osteoporosis Clinical criteria: Patient must have fracture due to minimal trauma, AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, AND Patient must not receive more than one PBS-subsidised treatment per year. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.							
9288W	zoledronic acid 5 mg/100 mL injection, 1 x 100 mL vial	1	..	..	589.51	37.70	Aclasta	NV

MUSCULO-SKELETAL SYSTEM

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ZOLEDRONIC ACID

Authority required (STREAMLINED)

4876

Symptomatic Paget disease of bone

Only 1 treatment each year per patient will be PBS-subsidised

9350D	zoledronic acid 5 mg/100 mL injection, 1 x 100 mL vial	1	..	..	589.51	37.70	Aclasta	NV

Bisphosphonates, combinations

ALENDRONATE + COLECALCIFEROL

Authority required (STREAMLINED)

4122

Corticosteroid-induced osteoporosis

Clinical criteria:

Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy,

AND

Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less,

AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

4133

Osteoporosis

Clinical criteria:

Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less,

AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

Population criteria:

Patient must be aged 70 years or older.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

4123

Established osteoporosis

Clinical criteria:

Patient must have fracture due to minimal trauma,

AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Note

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

9183H NP	alendronate 70 mg + colecalciferol 140 microgram tablet, 4	1	5	..	45.51	37.70	^a Alendronate D3 70 mg/140 microgram ^a Alendronate plus D3-DRLA ^a APO-Alendronate Plus D3 70 mg/140 mcg ^a Dronalen Plus ^a Fonat Plus	UA RZ TX GN AF

MUSCULO-SKELETAL SYSTEM

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				^b 2.49	48.00	37.70	^a Fosamax Plus 70 mg/140 mcg	MK

ALENDRONATE + COLECALCIFEROL

Authority required (STREAMLINED)

4070

Corticosteroid-induced osteoporosis

Clinical criteria:

Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy,

AND

Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less,

AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

4110

Osteoporosis

Clinical criteria:

Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less,

AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

Population criteria:

Patient must be aged 70 years or older.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

4087

Established osteoporosis

Clinical criteria:

Patient must have fracture due to minimal trauma,

AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Note

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

Note

Fosamax Plus provides a supplemental intake of vitamin D. The amount of colecalciferol present in Fosamax Plus is not sufficient to use as the sole treatment for correction of vitamin D deficiency.

9012H NP	alendronate 70 mg + colecalciferol 70 microgram tablet, 4	1	5	..	45.51	37.70	^a Alendronate D3 70 mg/70 microgram	UA
							^a Alendronate plus D3-DRLA	RZ
							^a APO-Alendronate Plus D3 70 mg/70 mcg	TX
							^a FonatPlus	AF
							^a Fosamax Plus	MK

ALENDRONATE + COLECALCIFEROL (&) CALCIUM CARBONATE

Authority required (STREAMLINED)

4122

Corticosteroid-induced osteoporosis

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$		Brand Name and Manufacturer	
Clinical criteria:									
Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy,									
AND									
Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less,									
AND									
Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.									
The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.									
<u>Authority required (STREAMLINED)</u>									
4133									
Osteoporosis									
Clinical criteria:									
Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less,									
AND									
Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.									
Population criteria:									
Patient must be aged 70 years or older.									
The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.									
<u>Authority required (STREAMLINED)</u>									
4123									
Established osteoporosis									
Clinical criteria:									
Patient must have fracture due to minimal trauma,									
AND									
Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.									
The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.									
A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.									
Note									
Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.									
9351E NP	alendronate 70 mg + colecalciferol 140 microgram tablet [4] (&) calcium (as carbonate) 500 mg tablet [48], 1 pack	#1	5	..	45.51	37.70	^a	Alendronate Plus D3 and Calcium Sandoz	SZ
							^a	Alendronate Plus D3 Calcium Actavis	UA
							^a	Dronalen Plus D-Cal	FR
							^a	Fosamax Plus D-Cal	MK
							^a	ReddyMax Plus D-Cal	RZ
RISEDRONATE (&) CALCIUM CARBONATE									
<u>Authority required (STREAMLINED)</u>									
4122									
Corticosteroid-induced osteoporosis									
Clinical criteria:									
Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy,									
AND									
Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less,									
AND									
Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.									
The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.									

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Authority required (STREAMLINED)

4133

Osteoporosis

Clinical criteria:

Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less,

AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

Population criteria:

Patient must be aged 70 years or older.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

4123

Established osteoporosis

Clinical criteria:

Patient must have fracture due to minimal trauma,

AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Note

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

8973G NP	RISEDRONATE SODIUM and CALCIUM CARBONATE Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium), 1	±1	5	..	45.73	37.70	Actonel EC Combi	UA
8899J NP	risedronate sodium 35 mg tablet [4] (& calcium (as carbonate) 500 mg tablet [24], 28	±1	5	..	45.73	37.70	Acris Combi	AF

RISEDRONATE (&) CALCIUM CARBONATE + COLECALCIFEROL

Authority required (STREAMLINED)

4122

Corticosteroid-induced osteoporosis

Clinical criteria:

Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy,

AND

Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less,

AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

4133

Osteoporosis

Clinical criteria:

Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less,

AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

MUSCULO-SKELETAL SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
Population criteria:								
Patient must be aged 70 years or older.								
The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.								
<u>Authority required (STREAMLINED)</u>								
4123								
Established osteoporosis								
Clinical criteria:								
Patient must have fracture due to minimal trauma,								
AND								
Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.								
The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.								
A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.								
<u>Note</u>								
Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.								
8974H NP	RISEDRONATE SODIUM and CALCIUM CARBONATE with COLECALCIFEROL Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms, 1	1	5	..	45.73	37.70	Actonel EC Combi D	UA
Other drugs affecting bone structure and mineralization								
CALCITRIOL								
<u>Authority required (STREAMLINED)</u>								
1165								
Hypocalcaemia due to renal disease								
<u>Authority required (STREAMLINED)</u>								
1166								
Hypoparathyroidism								
<u>Authority required (STREAMLINED)</u>								
1167								
Hypophosphataemic rickets								
<u>Authority required (STREAMLINED)</u>								
1467								
Vitamin D-resistant rickets								
<u>Authority required (STREAMLINED)</u>								
2636								
Treatment for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.								
A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body								
2502Q NP	calcitriol 0.25 microgram capsule, 100	1	3	..	30.62	31.77	^a Calciprox	ER
							^a Calcitriol AN	EA
							^a Calcitriol-GA	UA
							^a Calcitriol Sandoz	SZ
							^a GenRx Calcitriol	GX
							^a Kosteo	QA
							^a Rocaltrol	RO
							^a Sical	AF

MUSCULO-SKELETAL SYSTEM

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DENOSUMAB

Authority required (STREAMLINED)

4504

Giant cell tumour of bone

Clinical criteria:

Patient must be one in whom surgical resection is not feasible; OR

Patient must be one in whom surgical resection is possible but surgery would result in significant morbidity.

Population criteria:

Patient must be an adult; OR

Patient must be a skeletally mature adolescent.

Note

Denosumab is not PBS-subsidised for use in patients who have undergone curative surgical resection.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

10061M NP	denosumab 120 mg/1.7 mL injection, 1 x 1.7 mL vial	1	5	..	532.31	37.70	Xgeva	AN

DENOSUMAB

Authority required (STREAMLINED)

4158

Bone metastases

Clinical criteria:

The condition must be due to breast cancer.

Authority required (STREAMLINED)

4150

Bone metastases

Clinical criteria:

The condition must be due to castration-resistant prostate cancer.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

5110Y NP	denosumab 120 mg/1.7 mL injection, 1 x 1.7 mL vial	1	5	..	532.31	37.70	Xgeva	AN

DENOSUMAB

Authority required (STREAMLINED)

4314

Osteoporosis

Clinical criteria:

Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less,

AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

Population criteria:

Patient must be aged 70 years or older.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

4347

Established osteoporosis

Clinical criteria:

Patient must have fracture due to minimal trauma,

MUSCULO-SKELETAL SYSTEM

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AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Note

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

5457F NP	denosumab 60 mg/mL injection, 1 x 1 mL syringe	1	..	..	296.00	37.70	Prolia	AN

RALOXIFENE

Authority required (STREAMLINED)

4071

Established post-menopausal osteoporosis

Clinical criteria:

Patient must have fracture due to minimal trauma,

AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Note

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

8363E NP	raloxifene hydrochloride 60 mg tablet, 28	1	5	..	50.55	37.70	a APO-Raloxifene a Chem mart Raloxifene a Evifyne a Evista a Raloxifene AN a Terry White Chemists Raloxifene	TX CH EL LY EA TW

STRONTIUM

Authority required

Severe established osteoporosis

Clinical criteria:

Patient must have fracture due to minimal trauma,

AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition,

AND

Patient must be at high risk of fracture,

AND

Patient must be unable to use other medications for the treatment of osteoporosis due to contraindications or intolerance.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance

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imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Note

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

3036T	strontium ranelate 2 g granules, 28 x 2 g sachets	1	5	..	52.00	37.70	Protos 2 g	SE

TERIPARATIDE

Authority required

Severe established osteoporosis

Treatment Phase: Initial treatment

Clinical criteria:

Patient must be at very high risk of fracture,

AND

Patient must have a bone mineral density (BMD) T-score of -3.0 or less,

AND

Patient must have had 2 or more fractures due to minimal trauma,

AND

Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses,

AND

The treatment must be the sole PBS-subsidised agent,

AND

The treatment must not exceed a lifetime maximum of 18 months therapy.

Treatment criteria:

Must be treated by a specialist; OR

Must be treated by a consultant physician.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months, strontium ranelate 2 g per day and zoledronic acid 5 mg per annum.

Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be provided at the time of application.

Note

Details of accepted toxicities including severity can be found on the Department of Human Services website at www.humanservices.gov.au.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

Special Pricing Arrangements apply.

Authority required

Severe established osteoporosis

Treatment Phase: Continuing treatment

MUSCULO-SKELETAL SYSTEM

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Clinical criteria: Patient must have previously been issued with an authority prescription for this drug, AND The treatment must not exceed a lifetime maximum of 18 months therapy. Note Up to a maximum of 18 pens will be reimbursed through the PBS. Note No increase in the maximum quantity or number of units may be authorised. Note No increase in the maximum number of repeats may be authorised. Note Special Pricing Arrangements apply.							
9411H	teriparatide 20 microgram/dose injection, 1 x 2.4 mL cartridge	1	5	..	438.71	37.70	Forteo LY

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	

NERVOUS SYSTEM

ANALGESICS

OPIOIDS

Natural opium alkaloids

CODEINE

1214X NP	codeine phosphate 30 mg tablet, 20	1	..	..	17.21	18.36	Fawns and McAllan Proprietary Limited	FM

CODEINE

Note

Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

5063L DP	codeine phosphate 30 mg tablet, 20	1	..	..	17.21	18.36	Fawns and McAllan Proprietary Limited	FM

HYDROMORPHONE

Restricted benefit

Severe disabling pain not responding to non-narcotic analgesics

Caution

The risk of drug dependence is high.

Note

Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

5132D DP	hydromorphone hydrochloride 1 mg/mL oral liquid, 473 mL	1	..	..	64.04	37.70	Dilaudid	MF
5115F DP	hydromorphone hydrochloride 2 mg tablet, 20	1	..	..	17.45	18.60	Dilaudid	MF
5116G DP	hydromorphone hydrochloride 4 mg tablet, 20	1	..	..	20.19	21.34	Dilaudid	MF
5117H DP	hydromorphone hydrochloride 8 mg tablet, 20	1	..	..	30.37	31.52	Dilaudid	MF

HYDROMORPHONE

Restricted benefit

Severe disabling pain not responding to non-narcotic analgesics

Caution

The risk of drug dependence is high.

Note

Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or
- (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

8424J NP	hydromorphone hydrochloride 1 mg/mL oral liquid, 473 mL	1	..	..	64.04	37.70	Dilaudid	MF
8541M NP	hydromorphone hydrochloride 2 mg tablet, 20	1	..	..	17.45	18.60	Dilaudid	MF
8542N NP	hydromorphone hydrochloride 4 mg tablet, 20	1	..	..	20.19	21.34	Dilaudid	MF
8543P NP	hydromorphone hydrochloride 8 mg tablet, 20	1	..	..	30.37	31.52	Dilaudid	MF

HYDROMORPHONE

Caution

The risk of drug dependence is high.

8421F	hydromorphone hydrochloride 10	1	..	..	29.31	30.46	Dilaudid-HP	MF

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
NP	mg/mL injection, 5 x 1 mL ampoules							
8420E	hydromorphone hydrochloride 2	1	..	..	23.18	24.33	Dilaudid	MF
NP	mg/mL injection, 5 x 1 mL ampoules							
8422G	hydromorphone hydrochloride 50 mg/5	1	..	..	52.34	37.70	Dilaudid-HP	MF
NP	mL injection, 5 x 5 mL ampoules							
8423H	hydromorphone hydrochloride 500	1	..	..	75.75	37.70	Dilaudid-HP	MF
NP	mg/50 mL injection, 1 x 50 mL vial							

HYDROMORPHONE

Restricted benefit

Chronic severe disabling pain not responding to non-narcotic analgesics

Caution

The risk of drug dependence is high.

Note

Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) chronic severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or
- (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

9407D	hydromorphone hydrochloride 16 mg	1	..	..	53.16	37.70	Jurnista	JC
NP	tablet: modified release, 14 tablets							
9408E	hydromorphone hydrochloride 32 mg	1	..	..	89.04	37.70	Jurnista	JC
NP	tablet: modified release, 14 tablets							
9299K	hydromorphone hydrochloride 4 mg	1	..	..	31.29	32.44	Jurnista	JC
NP	tablet: modified release, 14 tablets							
9409F	hydromorphone hydrochloride 64 mg	1	..	..	149.72	37.70	Jurnista	JC
NP	tablet: modified release, 14 tablets							
9406C	hydromorphone hydrochloride 8 mg	1	..	..	36.75	37.70	Jurnista	JC
NP	tablet: modified release, 14 tablets							

MORPHINE

Restricted benefit

Chronic severe disabling pain not responding to non-narcotic analgesics

Caution

The risk of drug dependence is high.

Note

Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) chronic severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or
- (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

8349K	morphine Capsule 10 mg (containing	1	..	..	20.37	21.52	Kapanol	YN
NP	sustained release pellets), 28							
2841M	morphine Capsule 100 mg (containing	1	..	..	70.81	37.70	Kapanol	YN
NP	sustained release pellets), 28							
2839K	morphine Capsule 20 mg (containing	1	..	..	25.35	26.50	Kapanol	YN
NP	sustained release pellets), 28							
2840L	morphine Capsule 50 mg (containing	1	..	..	43.65	37.70	Kapanol	YN
NP	sustained release pellets), 28							
8146R	morphine Sachet containing controlled	1	..	..	62.41	37.70	MS Contin Suspension	MF
NP	release granules for oral suspension, 30 mg per sachet, 28						30 mg	

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
8305D NP	morphine Sachet containing controlled release granules for oral suspension, 60 mg per sachet, 28	1	..	..	70.21	37.70	MS Contin Suspension 60 mg	MF
1653B NP	morphine sulfate 10 mg tablet: modified release, 28 tablets	1	..	..	20.38	21.53	^a Momex SR 10	QA
							^a MORPHINE MR APOTEX	TX
							^a MS Contin	MF
8306E NP	morphine sulfate 100 mg granules: modified release, 28 sachets	1	..	..	86.71	37.70	MS Contin Suspension 100 mg	MF
1656E NP	morphine sulfate 100 mg tablet: modified release, 28 tablets	1	..	..	72.85	37.70	^a APOTEX-MORPHINE MR	TX
							^a Momex SR 100	QA
							^a MS Contin	MF
8494C NP	morphine sulfate 120 mg capsule: modified release, 14 capsules	1	..	..	54.81	37.70	MS Mono	MF
8489T NP	morphine sulfate 15 mg tablet: modified release, 28 tablets	1	..	..	24.57	25.72	MS Contin	MF
8490W NP	morphine sulfate 20 mg granules: modified release, 28 sachets	1	..	..	60.63	37.70	MS Contin Suspension 20 mg	MF
8491X NP	morphine sulfate 30 mg capsule: modified release, 14 capsules	1	..	..	24.56	25.71	MS Mono	MF
1654C NP	morphine sulfate 30 mg tablet: modified release, 28 tablets	1	..	..	36.23	37.38	^a Momex SR 30	QA
							^a MORPHINE MR APOTEX	TX
							^a MS Contin	MF
8035X NP	morphine sulfate 5 mg tablet: modified release, 28 tablets	1	..	..	17.95	19.10	MS Contin	MF
8492Y NP	morphine sulfate 60 mg capsule: modified release, 14 capsules	1	..	..	36.21	37.36	MS Mono	MF
1655D NP	morphine sulfate 60 mg tablet: modified release, 28 tablets	1	..	..	54.82	37.70	^a Momex SR 60	QA
							^a MORPHINE MR APOTEX	TX
							^a MS Contin	MF
8493B NP	morphine sulfate 90 mg capsule: modified release, 14 capsules	1	..	..	41.76	37.70	MS Mono	MF

MORPHINE

Restricted benefit

Severe disabling pain not responding to non-narcotic analgesics

Caution

The risk of drug dependence is high.

Note

Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or
- (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

2124T NP	morphine hydrochloride 10 mg/mL oral liquid, 200 mL	1	..	..	27.20	28.35	Ordine 10	MF
2122Q NP	morphine hydrochloride 2 mg/mL oral liquid, 200 mL	1	..	..	20.67	21.82	Ordine 2	MF
2123R NP	morphine hydrochloride 5 mg/mL oral liquid, 200 mL	1	..	..	23.07	24.22	Ordine 5	MF
1646P NP	morphine sulfate 30 mg tablet, 20	1	..	..	14.37	15.52	Anamorph	FM

MORPHINE

Restricted benefit

Severe disabling pain not responding to non-narcotic analgesics

Caution

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
The risk of drug dependence is high.								
Note								
Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.								
5239R DP	morphine hydrochloride 10 mg/mL oral liquid, 200 mL	1	..	..	27.20	28.35	Ordine 10	MF
5237P DP	morphine hydrochloride 2 mg/mL oral liquid, 200 mL	1	..	..	20.67	21.82	Ordine 2	MF
5238Q DP	morphine hydrochloride 5 mg/mL oral liquid, 200 mL	1	..	..	23.07	24.22	Ordine 5	MF
5163R DP	morphine sulfate 30 mg tablet, 20	1	..	..	14.37	15.52	Anamorph	FM
MORPHINE								
Restricted benefit								
Severe disabling pain due to cancer not responding to non-narcotic analgesics								
Caution								
The risk of drug dependence is high.								
8669G NP	morphine sulfate 10 mg tablet, 20	1	..	..	14.66	15.81	Sevredol	MF
8670H NP	morphine sulfate 20 mg tablet, 20	1	..	..	15.60	16.75	Sevredol	MF
MORPHINE								
Caution								
The risk of drug dependence is high.								
1644M NP,MW	morphine sulfate 10 mg/mL injection, 5 x 1 mL ampoules	1	..	..	16.76	17.91	Hospira Pty Limited	HH
1645N NP,MW	morphine sulfate 15 mg/mL injection, 5 x 1 mL ampoules	1	..	..	17.30	18.45	Hospira Pty Limited	HH
1647Q NP	morphine sulfate 30 mg/mL injection, 5 x 1 mL ampoules	1	..	..	19.43	20.58	Hospira Pty Limited	HH
1607N NP	morphine tartrate 120 mg/1.5 mL injection, 5 x 1.5 mL ampoules	1	..	..	39.62	37.70	Hospira Pty Limited	HH
MORPHINE								
Caution								
The risk of drug dependence is high.								
Note								
Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.								
5168B DP	morphine sulfate 10 mg/mL injection, 5 x 1 mL ampoules	1	..	..	16.76	17.91	Hospira Pty Limited	HH
5169C DP	morphine sulfate 15 mg/mL injection, 5 x 1 mL ampoules	1	..	..	17.30	18.45	Hospira Pty Limited	HH
5170D DP	morphine sulfate 30 mg/mL injection, 5 x 1 mL ampoules	1	..	..	19.43	20.58	Hospira Pty Limited	HH
MORPHINE								
Authority required								
Chronic severe disabling pain due to cancer								
Caution								
The risk of drug dependence is high.								
8454Y NP	morphine sulfate 200 mg granules: modified release, 28 sachets	1	..	..	164.09	37.70	MS Contin Suspension 200 mg	MF
8453X NP	morphine sulfate 200 mg tablet: modified release, 28 tablets	1	..	..	122.20	37.70	MS Contin	MF

OXYCODONE

Restricted benefit

Severe disabling pain not responding to non-narcotic analgesics

Caution

The risk of drug dependence is high.

Note

Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) severe disabling pain associated with proven malignant neoplasia; or

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or							
	(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or							
	(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.							
2481N NP	oxycodone 30 mg suppository, 12	1	..	..	44.00	37.70	Proladone	PL
8501K NP	oxycodone hydrochloride 10 mg capsule, 20	1	..	..	14.76	15.91	OxyNorm	MF
8502L NP	oxycodone hydrochloride 20 mg capsule, 20	1	..	..	18.72	19.87	OxyNorm	MF
8464L NP	oxycodone hydrochloride 5 mg capsule, 20	1	..	..	12.14	13.29	OxyNorm	MF
2622B NP	oxycodone hydrochloride 5 mg tablet, 20	1	..	..	12.14	13.29	Endone	QA
8644Y NP	oxycodone hydrochloride 5 mg/5 mL oral liquid, 250 mL	1	..	..	21.07	22.22	OxyNorm Liquid 5mg/5mL	MF

OXYCODONE

Restricted benefit

Severe disabling pain not responding to non-narcotic analgesics

Caution

The risk of drug dependence is high.

Note

Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

5194J DP	oxycodone 30 mg suppository, 12	1	..	..	44.00	37.70	Proladone	PL
5197M DP	oxycodone hydrochloride 10 mg capsule, 20	1	..	..	14.76	15.91	OxyNorm	MF
5191F DP	oxycodone hydrochloride 5 mg capsule, 20	1	..	..	12.14	13.29	OxyNorm	MF
5195K DP	oxycodone hydrochloride 5 mg tablet, 20	1	..	..	12.14	13.29	Endone	QA
5190E DP	oxycodone hydrochloride 5 mg/5 mL oral liquid, 250 mL	1	..	..	21.07	22.22	OxyNorm Liquid 5mg/5mL	MF

OXYCODONE

Restricted benefit

Chronic severe disabling pain

Clinical criteria:

The condition must be unresponsive to non-narcotic analgesics.

Caution

The risk of drug dependence is high.

Note

Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Note

OxyContin modified release tablets are intended to be crush-deterrent and to reduce the rapid release of oxycodone upon accidental or intentional misuse.

8385H NP	oxycodone hydrochloride 10 mg tablet: modified release, 28 tablets	1	..	..	24.57	25.72 ^a	Oxycodone Sandoz	SZ

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
9399Q NP	oxycodone hydrochloride 15 mg tablet: modified release, 28 tablets	1	..	..	31.60	32.75	^a OxyContin	MF
8386J NP	oxycodone hydrochloride 20 mg tablet: modified release, 28 tablets	1	..	..	36.22	37.37	^a Oxycodone Sandoz	SZ
9400R NP	oxycodone hydrochloride 30 mg tablet: modified release, 28 tablets	1	..	..	46.79	37.70	^a OxyContin	MF
8387K NP	oxycodone hydrochloride 40 mg tablet: modified release, 28 tablets	1	..	..	54.81	37.70	^a Oxycodone Sandoz	SZ
8388L NP	oxycodone hydrochloride 80 mg tablet: modified release, 28 tablets	1	..	..	83.05	37.70	^a OxyContin	MF
							^a Oxycodone Sandoz	SZ
							^a OxyContin	MF

OXYCODONE + NALOXONE

Restricted benefit

Chronic severe disabling pain not responding to non-narcotic analgesics

Caution

The risk of drug dependence is high.

Note

Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) chronic severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or
- (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8934F NP	oxycodone hydrochloride 10 mg + naloxone hydrochloride 5 mg tablet: modified release, 28 tablets	1	..	..	31.01	32.16	Targin 10/5mg	MF
8935G NP	oxycodone hydrochloride 20 mg + naloxone hydrochloride 10 mg tablet: modified release, 28 tablets	1	..	..	47.19	37.70	Targin 20/10mg	MF
8936H NP	oxycodone hydrochloride 40 mg + naloxone hydrochloride 20 mg tablet: modified release, 28 tablets	1	..	..	73.62	37.70	Targin 40/20mg	MF
8000C NP	oxycodone hydrochloride 5 mg + naloxone hydrochloride 2.5 mg tablet: modified release, 28 tablets	1	..	..	29.71	30.86	Targin 5/2.5mg	MF

PARACETAMOL + CODEINE

Note

Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of codeine phosphate with paracetamol below.

1215Y NP	CODEINE PHOSPHATE with PARACETAMOL Tablet 30 mg-500 mg, 20	1	..	..	7.68	8.83	^a APO-Paracetamol/Codeine 500/30	TX
							^a Codalgin Forte	FM
							^a Codapane Forte	AL
							^a Comfarol Forte	SZ
							^a Paracetamol/Codeine GH 500/30	GQ
							^a Prodeine Forte	AV
				^b 2.40	10.08	8.83	^a Panadeine Forte	SW

PARACETAMOL + CODEINE

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
3316M DP	CODEINE PHOSPHATE with PARACETAMOL Tablet 30 mg-500 mg, 20	1	..	..	7.68	8.83	^a APO-Paracetamol/Codeine 500/30	TX
							^a Codalgin Forte	FM
							^a Codapane Forte	AL
							^a Comfarol Forte	SZ
							^a Paracetamol/Codeine GH 500/30	GQ
				^b 2.40	10.08	8.83	^a Prodeine Forte	AV
							^a Panadeine Forte	SW

PARACETAMOL + CODEINE

Authority required

Severe disabling pain not responding to non-narcotic analgesics

Note

Each authority approval will be limited to no more than 240 tablets per month for no more than 6 months.

8785J NP	CODEINE PHOSPHATE with PARACETAMOL Tablet 30 mg-500 mg, 20	3	..	..	*9.52	10.67	^a APO-Paracetamol/Codeine 500/30	TX
							^a Codalgin Forte	FM
							^a Codapane Forte	AL
							^a Comfarol Forte	SZ
							^a Paracetamol/Codeine GH 500/30	GQ
				^b 7.20	*16.72	10.67	^a Prodeine Forte	AV
							^a Panadeine Forte	SW

Phenylpiperidine derivatives

FENTANYL

Restricted benefit

Chronic severe disabling pain not responding to non-narcotic analgesics

Caution

The risk of drug dependence is high.

Note

Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) chronic severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or
- (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Note

Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain, because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Pharmaceutical benefits that have the forms fentanyl transdermal patch 16.5 mg, fentanyl transdermal patch 10.20 mg and fentanyl transdermal patch 16.8 mg (all releasing approximately 100 micrograms per hour) are equivalent for the purposes of substitution.

5280X NP	fentanyl 100 microgram/hour patch, 5	1	..	..	69.30	37.70	^a Denpax	AF
5441J NP	fentanyl 100 microgram/hour patch, 5	1	..	..	69.30	37.70	^a Dutran 100	GN
							^a Fenpatch 100	ZP
8894D NP	fentanyl 100 microgram/hour patch, 5	1	..	..	69.30	37.70	^a Durogesic 100	JC
							^a Fentanyl Sandoz	SZ

FENTANYL

Restricted benefit

Chronic severe disabling pain not responding to non-narcotic analgesics

Caution

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
The risk of drug dependence is high.							
Note							
Authorities for increased maximum quantities and/or repeats will be granted only for:							
(i) chronic severe disabling pain associated with proven malignant neoplasia; or							
(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or							
(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or							
(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.							
Note							
Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain, because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).							
Pharmaceutical benefits that have the forms fentanyl transdermal patch 2.063 mg, fentanyl transdermal patch 1.28 mg and fentanyl transdermal patch 2.1 mg (all releasing approximately 12 micrograms per hour) are equivalent for the purposes of substitution.							
5265D NP	fentanyl 12 microgram/hour patch, 5	1	..	..	25.21	26.36	^a Denpax AF
5437E NP	fentanyl 12 microgram/hour patch, 5	1	..	..	25.21	26.36	^a Dutran 12 GN
8878G NP	fentanyl 12 microgram/hour patch, 5	1	..	..	25.21	26.36	^a Fenpatch 12 ZP
							^a Durogesic 12 JC
							^a Fentanyl Sandoz SZ

FENTANYL

Restricted benefit

Chronic severe disabling pain not responding to non-narcotic analgesics

Caution

The risk of drug dependence is high.

Note

Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) chronic severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or
- (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Note

Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain, because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Pharmaceutical benefits that have the forms fentanyl transdermal patch 4.125 mg, fentanyl transdermal patch 2.55 mg and fentanyl transdermal patch 4.2 mg (all releasing approximately 25 micrograms per hour) are equivalent for the purposes of substitution.

5277R NP	fentanyl 25 microgram/hour patch, 5	1	..	..	29.49	30.64	^a Denpax AF
5438F NP	fentanyl 25 microgram/hour patch, 5	1	..	..	29.49	30.64	^a Dutran 25 GN
8891Y NP	fentanyl 25 microgram/hour patch, 5	1	..	..	29.49	30.64	^a Fenpatch 25 ZP
							^a Durogesic 25 JC
							^a Fentanyl Sandoz SZ

FENTANYL

Restricted benefit

Chronic severe disabling pain not responding to non-narcotic analgesics

Caution

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	The risk of drug dependence is high.						
	Note						
	Authorities for increased maximum quantities and/or repeats will be granted only for:						
	(i) chronic severe disabling pain associated with proven malignant neoplasia; or						
	(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or						
	(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or						
	(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.						
	Note						
	Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain, because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).						
	Pharmaceutical benefits that have the forms fentanyl transdermal patch 8.25 mg, fentanyl transdermal patch 5.10 mg and fentanyl transdermal patch 8.4 mg (all releasing approximately 50 micrograms per hour) are equivalent for the purposes of substitution.						
5278T NP	fentanyl 50 microgram/hour patch, 5	1	..	..	45.96	37.70	^a Denpax AF
5439G NP	fentanyl 50 microgram/hour patch, 5	1	..	..	45.96	37.70	^a Dutran 50 GN
8892B NP	fentanyl 50 microgram/hour patch, 5	1	..	..	45.96	37.70	^a Fenpatch 50 ZP
						^a Durogesic 50 JC	
						^a Fentanyl Sandoz SZ	

FENTANYL

Restricted benefit

Chronic severe disabling pain not responding to non-narcotic analgesics

Caution

The risk of drug dependence is high.

Note

Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) chronic severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or
- (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Note

Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain, because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Pharmaceutical benefits that have the forms fentanyl transdermal patch 12.375 mg, fentanyl transdermal patch 7.65 mg and fentanyl transdermal patch 12.6 mg (all releasing approximately 75 micrograms per hour) are equivalent for the purposes of substitution.

5279W NP	fentanyl 75 microgram/hour patch, 5	1	..	..	57.81	37.70	^a Denpax	AF
5440H NP	fentanyl 75 microgram/hour patch, 5	1	..	..	57.81	37.70	^a Dutran 75	GN
8893C NP	fentanyl 75 microgram/hour patch, 5	1	..	..	57.81	37.70	^a Fenpatch 75	ZP
							^a Durogesic 75	JC
							^a Fentanyl Sandoz	SZ

Diphenylpropylamine derivatives

METHADONE

Restricted benefit

Severe disabling pain not responding to non-narcotic analgesics

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
Caution								
The risk of drug dependence is high.								
Note								
Authorities for increased maximum quantities and/or repeats will be granted only for:								
(i) severe disabling pain associated with proven malignant neoplasia; or								
(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or								
(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or								
(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.								
Note								
Shared Care Model:								
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
1609Q NP	methadone hydrochloride 10 mg tablet, 20	1	..	..	15.57	16.72	Physeptone	QA
1606M NP	methadone hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules	1	..	..	49.65	37.70	Physeptone	QA

Oripavine derivatives

BUPRENORPHINE

Restricted benefit

Chronic severe disabling pain not responding to non-narcotic analgesics

Caution

The risk of drug dependence is high.

Note

Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) chronic severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or
- (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
- (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8866P NP	buprenorphine 10 microgram/hour patch, 2	1	..	..	41.11	37.70	Norspan	MF
8867Q NP	buprenorphine 20 microgram/hour patch, 2	1	..	..	56.42	37.70	Norspan	MF
8865N NP	buprenorphine 5 microgram/hour patch, 2	1	..	..	27.04	28.19	Norspan	MF

Other opioids

TAPENTADOL

Restricted benefit

Chronic severe disabling pain

Clinical criteria:

The condition must be unresponsive to non-narcotic analgesics.

Caution

The risk of drug dependence is high.

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
Note								
Authorities for increased maximum quantities and/or repeats will be granted only for:								
(i) chronic severe disabling pain associated with proven malignant neoplasia; or								
(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or								
(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or								
(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.								
10094G NP	tapentadol 100 mg tablet: modified release, 28	1	..	..	31.65	32.80	Palexia SR	CS
10100N NP	tapentadol 150 mg tablet: modified release, 28	1	..	..	40.35	37.70	Palexia SR	CS
10091D NP	tapentadol 200 mg tablet: modified release, 28	1	..	..	47.49	37.70	Palexia SR	CS
10092E NP	tapentadol 250 mg tablet: modified release, 28	1	..	..	53.15	37.70	Palexia SR	CS
10096J NP	tapentadol 50 mg tablet: modified release, 28	1	..	..	22.60	23.75	Palexia SR	CS
TRAMADOL								
Restricted benefit								
For pain where aspirin and/or paracetamol alone are inappropriate or have failed								
Note								
Authorities for increased maximum quantities and/or repeats will be granted only for severe disabling pain not responding to non-narcotic analgesics.								
8523N NP	tramadol hydrochloride 100 mg tablet: modified release, 20 tablets	1	..	..	9.89	11.04	^a APO-Tramadol SR	TX
							^a Chem mart Tramadol SR	CH
							^a GA Tramadol SR 100mg	GN
							^a Lodam SR 100	ZP
							^a Terry White Chemists Tramadol SR	TW
							^a Tramadol AN SR	EA
							^a Tramadol Sandoz SR	SZ
							^a Tramadol SR generichealth	GQ
							^a Tramedo SR 100	AF
				^B 3.83	13.72	11.04	^a Zydol SR 100	QA
							^a Tramal SR 100	CS
8843K NP	tramadol hydrochloride 100 mg/mL oral liquid, 10 mL	≠1	..	..	14.05	15.20	Tramal	CS
8524P NP	tramadol hydrochloride 150 mg tablet: modified release, 20 tablets	1	..	..	10.97	12.12	^a APO-Tramadol SR	TX
							^a Chem mart Tramadol SR	CH
							^a GA Tramadol SR 150mg	GN
							^a Lodam SR 150	ZP
							^a Terry White Chemists Tramadol SR	TW
							^a Tramadol AN SR	EA
							^a Tramadol Sandoz SR	SZ
							^a Tramadol SR generichealth	GQ
							^a Tramedo SR 150	AF
				^B 4.58	15.55	12.12	^a Zydol SR 150	QA
8525Q NP	tramadol hydrochloride 200 mg tablet: modified release, 20 tablets	1	..	..	11.88	13.03	^a Tramal SR 150	CS
							^a APO-Tramadol SR	TX
							^a Chem mart Tramadol SR	CH
							^a GA Tramadol SR 200mg	GN

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							^a Terry White Chemists	TW
							Tramadol SR	
							^a Tramadol AN SR	EA
							^a Tramadol Sandoz SR	SZ
							^a Tramadol SR	GQ
							generichealth	
							^a Tramedo SR 200	AF
							^a Zydol SR 200	QA
				^b 5.20	17.08	13.03	^a Tramal SR 200	CS
2527B NP	tramadol hydrochloride 50 mg tablet: modified release, 20 tablets	1	..	..	10.38	11.53	Tramal SR 50	CS
	TRAMADOL							
	<u>Restricted benefit</u>							
	Short-term treatment of acute pain							
5231H DP	tramadol hydrochloride 100 mg/2 mL injection, 5 x 2 mL ampoules	1	..	..	11.92	13.07	^a Tramadol ACT	GN
							^a Tramadol Sandoz	SZ
							^a Tramal 100	CS
	TRAMADOL							
	<u>Restricted benefit</u>							
	Short-term treatment of acute pain							
	<u>Note</u>							
	No applications for increased maximum quantities and/or repeats will be authorised.							
8582Q NP	tramadol hydrochloride 100 mg/2 mL injection, 5 x 2 mL ampoules	1	..	..	11.92	13.07	^a Tramadol ACT	GN
							^a Tramadol Sandoz	SZ
							^a Tramal 100	CS
	TRAMADOL							
	<u>Restricted benefit</u>							
	For pain where aspirin and/or paracetamol alone are inappropriate or have failed							
5150C DP	tramadol hydrochloride 100 mg/mL oral liquid, 10 mL	1	..	..	14.05	15.20	Tramal	CS
	TRAMADOL							
	<u>Restricted benefit</u>							
	For acute pain where aspirin and/or paracetamol alone are inappropriate or have failed							
	<u>Restricted benefit</u>							
	For dosage titration in chronic pain where aspirin and/or paracetamol alone are inappropriate or have failed							
5232J DP	tramadol hydrochloride 50 mg capsule, 20	1	..	..	7.91	9.06	^a APO-Tramadol	TX
							^a Chem mart Tramadol	CH
							^a GA Tramadol 50mg	GN
							^a Terry White Chemists	TW
							Tramadol	
							^a Tramadol Actavis	UA
							^a Tramadol AN	EA
							^a Tramadol Sandoz	SZ
							^a Tramadol SCP	CR
							^a Tramedo	AF
							^a Zydol	QA
				^b 2.05	9.96	9.06	^a Tramal	CS
	TRAMADOL							
	<u>Restricted benefit</u>							
	For acute pain where aspirin and/or paracetamol alone are inappropriate or have failed							
	<u>Note</u>							
	No applications for increased maximum quantities and/or repeats will be authorised.							
8455B NP	tramadol hydrochloride 50 mg capsule, 20	1	..	..	7.91	9.06	^a APO-Tramadol	TX
							^a Chem mart Tramadol	CH
							^a GA Tramadol 50mg	GN

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							^a Terry White Chemists Tramadol	TW
							^a Tramadol Actavis	UA
							^a Tramadol AN	EA
							^a Tramadol Sandoz	SZ
							^a Tramadol SCP	CR
							^a Tramedo	AF
							^a Zydol	QA
				^B 2.05	9.96	9.06	^a Tramal	CS

TRAMADOL

Restricted benefit

For dosage titration in chronic pain where aspirin and/or paracetamol alone are inappropriate or have failed

Note

No applications for increased maximum quantities and/or repeats will be authorised.

8611F NP	tramadol hydrochloride 50 mg capsule, 20	1	2	..	7.91	9.06	^a APO-Tramadol	TX
							^a Chem mart Tramadol	CH
							^a GA Tramadol 50mg	GN
							^a Terry White Chemists Tramadol	TW
							^a Tramadol Actavis	UA
							^a Tramadol AN	EA
							^a Tramadol Sandoz	SZ
							^a Tramadol SCP	CR
							^a Tramedo	AF
							^a Zydol	QA
				^B 2.05	9.96	9.06	^a Tramal	CS

OTHER ANALGESICS AND ANTIPYRETICS

Salicylic acid and derivatives

ASPIRIN

1010E NP	aspirin 300 mg tablet: effervescent, 96	1	1	..	8.51	9.66	Solprin	RC
5018D DP	aspirin 300 mg tablet: effervescent, 96	1	..	..	8.51	9.66	Solprin	RC

Anilides

PARACETAMOL

1747Y NP	paracetamol 120 mg/5 mL oral liquid, 100 mL	‡1	2	..	9.72	10.87	Panamax	SW
3348F DP	paracetamol 120 mg/5 mL oral liquid, 100 mL	‡1	..	..	9.72	10.87	Panamax	SW
1770E NP	paracetamol 240 mg/5 mL oral liquid, 200 mL	‡1	2	..	11.02	12.17	Panamax 240 Elixir	SW
3349G DP	paracetamol 240 mg/5 mL oral liquid, 200 mL	‡1	..	..	11.02	12.17	Panamax 240 Elixir	SW
1746X NP	paracetamol 500 mg tablet, 100	1	1	..	8.66	9.81	^a APO-Paracetamol	TX
							^a Febridol	GN
							^a Generic Health Pty Ltd	GQ
							^a Panamax	SW
							^a Paracetamol (Sandoz)	SZ
							^a Paralgin	FM
							^a Parapane	AF
5196L DP	paracetamol 500 mg tablet, 100	1	..	..	8.66	9.81	^a APO-Paracetamol	TX
							^a Febridol	GN
							^a Generic Health Pty Ltd	GQ
							^a Panamax	SW
							^a Paracetamol (Sandoz)	SZ
							^a Paralgin	FM
							^a Parapane	AF

PARACETAMOL

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
Restricted benefit								
Chronic arthropathies								
5224Y DP	paracetamol 500 mg tablet, 100	3	..	..	*12.46	13.61	^a APO-Paracetamol	TX
							^a Febridol	GN
							^a Generic Health Pty Ltd	GQ
							^a Panamax	SW
							^a Paracetamol (Sandoz)	SZ
							^a Paralgin	FM
							^a Parapane	AF
8784H NP	paracetamol 500 mg tablet, 100	3	4	..	*12.46	13.61	^a APO-Paracetamol	TX
							^a Febridol	GN
							^a Generic Health Pty Ltd	GQ
							^a Panamax	SW
							^a Paracetamol (Sandoz)	SZ
							^a Paralgin	FM
							^a Parapane	AF
PARACETAMOL								
Restricted benefit								
Relief of persistent pain associated with osteoarthritis								
8814X NP	paracetamol 665 mg tablet: modified release, 96 tablets	2	5	..	*15.34	16.49	^a Osteomol 665 Paracetamol	CR
				^B 1.64	*16.98	16.49	^a Panadol Osteo	GC

Other analgesics and antipyretics

PREGABALIN

Authority required (STREAMLINED)

4172

Neuropathic pain

Clinical criteria:

The condition must be refractory to treatment with other drugs.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2355Y NP	pregabalin 150 mg capsule, 56	1	5	..	70.63	37.70	Lyrica	PF
2348N NP	pregabalin 25 mg capsule, 56	1	5	..	26.44	27.59	Lyrica	PF
2363J NP	pregabalin 300 mg capsule, 56	1	5	..	102.05	37.70	Lyrica	PF
2335X NP	pregabalin 75 mg capsule, 56	1	5	..	49.11	37.70	Lyrica	PF

ANTIMIGRAINE PREPARATIONS

Selective serotonin (5HT₁) agonists

ELETRIPTAN

Authority required (STREAMLINED)

4573

Migraine attack

Clinical criteria:

The condition must have usually failed to respond to analgesics in the past.

Caution

Selective serotonin (5HT₁) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

5290K NP	eletriptan 40 mg tablet, 4	1	5	..	25.10	26.25	Relpax	PF
5291L NP	eletriptan 80 mg tablet, 4	1	5	..	25.10	26.25	Relpax	PF

NARATRIPTAN

Authority required

Migraine attack

Clinical criteria:

The condition must have usually failed to respond to analgesics in the past.

Caution

Selective serotonin (5HT₁) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8298R NP	naratriptan 2.5 mg tablet, 2	2	5	\$2.78	*29.02	27.39	Naramig	AS

NARATRIPTAN

Authority required

Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics, and where adverse events have occurred with other suitable PBS-listed drugs

Authority required

Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics, and where drug interactions have occurred with other suitable PBS-listed drugs

Authority required

Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics, and where drug interactions are expected to occur with other suitable PBS-listed drugs

Authority required

Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics, and where transfer to another suitable PBS-listed drug would cause patient confusion resulting in problems with compliance

Authority required

Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics, and where transfer to another suitable PBS-listed drug is likely to result in adverse clinical consequences

Caution

Naratriptan is contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

9734H NP	naratriptan 2.5 mg tablet, 2	2	5	..	*29.02	30.17	Naramig	AS

RIZATRIPTAN

Authority required (STREAMLINED)

4573

Migraine attack

Clinical criteria:

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
The condition must have usually failed to respond to analgesics in the past.							
Caution							
Selective serotonin (5HT ₁) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.							
Note							
No increase in the maximum quantity or number of units may be authorised.							
Note							
No increase in the maximum number of repeats may be authorised.							
Note							
Continuing Therapy Only:							
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
9313E NP	rizatriptan 10 mg wafer, 2	2	5	..	*25.46	26.61	Maxalt MK
SUMATRIPTAN							
Authority required (STREAMLINED)							
4558							
Migraine attack							
Clinical criteria:							
The condition must have usually failed to respond to analgesics in the past.							
Caution							
Selective serotonin (5HT ₁) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.							
Note							
No increase in the maximum quantity or number of units may be authorised.							
Note							
No increase in the maximum number of repeats may be authorised.							
Note							
Pharmaceutical benefits that have the form sumatriptan tablet 50 mg (as succinate) and pharmaceutical benefits that have the form sumatriptan tablet (fast disintegrating) 50 mg (as succinate) are equivalent for the purposes of substitution.							
Note							
Continuing Therapy Only:							
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
8885P NP	SUMATRIPTAN Tablet (fast disintegrating) 50 mg (as succinate), 2	2	5	^B 2.04	*16.76	15.87	^a Imigran FDT AS
8144P NP	SUMATRIPTAN Tablet 50 mg (as succinate), 2	2	5	..	*14.72	15.87	^a APO-Sumatriptan TX
							^a Chem mart Sumatriptan CH
							^a Iptam AL
							^a Sumagran Aspen 50 AS
							^a Sumatab AF
							^a Sumatran QA
							^a Sumatriptan Sandoz SZ
							^a Terry White Chemists Sumatriptan TW
				^B 2.04	*16.76	15.87	^a Imigran LN
8341B NP	sumatriptan 20 mg/actuation nasal spray, 2 actuations	1	5	..	19.59	20.74	Imigran AS
1849H NP	sumatriptan 50 mg tablet, 4	1	5	..	14.72	15.87	^a APO-Sumatriptan TX
							^a Chem mart Sumatriptan CH
							^a Iptam AL
							^a Pharmacor Sumatriptan 50 CR
							^a Sumatran QA
							^a Sumatriptan AN EA
							^a Sumatriptan-GA GN
							^a Sumatriptan generichealth GQ

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							^a Sumatriptan RBX	RA
							^a Sumatriptan Sandoz	SZ
							^a Terry White Chemists Sumatriptan	TW
ZOLMITRIPTAN								
<u>Authority required (STREAMLINED)</u>								
4573								
Migraine attack								
Clinical criteria:								
The condition must have usually failed to respond to analgesics in the past.								
<u>Caution</u>								
Selective serotonin (5HT ₁) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.								
<u>Note</u>								
No increase in the maximum quantity or number of units may be authorised.								
<u>Note</u>								
No increase in the maximum number of repeats may be authorised.								
<u>Note</u>								
Continuing Therapy Only:								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8266C NP	zolmitriptan 2.5 mg tablet, 2	2	5	..	*26.18	27.33	^a APO-Zolmitriptan	TX
				^b 2.76	*28.94	27.33	^a Zoltrip	QA
							^a Zomig	AP

Other antimigraine preparations

CYPROHEPTADINE

Restricted benefit

Prevention of migraine

Note

Cyproheptadine hydrochloride is not PBS-subsidised for use in hay fever or atopy.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1798P NP	cyproheptadine hydrochloride 4 mg tablet, 100	1	2	..	14.53	15.68	Periactin	AS

PIZOTIFEN

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

3074T NP	pizotifen 500 microgram tablet, 100	1	2	..	22.09	23.24	Sandomigran 0.5	NV

ANTIEPILEPTICS

ANTIEPILEPTICS

Barbiturates and derivatives

PHENOBARBITONE

Restricted benefit

Epilepsy

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1850J	phenobarbitone 30 mg tablet, 200	1	4	..	16.94	18.09	Aspen Pharma Pty Ltd	QA

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
NP 2138M NP	phenobarbitone sodium 219 mg/mL injection, 5 x 1 mL ampoules	1	..	..	39.36	37.70	Fawns and McAllan Proprietary Limited	FM

PRIMIDONE

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

NP 1939C NP	primidone 250 mg tablet, 200	1	2	..	83.83	37.70	Mysoline	LM

Hydantoin derivatives

PHENYTOIN

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

NP 2692Q NP	phenytoin 30 mg/5 mL oral liquid, 500 mL	1	3	..	30.62	31.77	Dilantin	PF
NP 1249R NP	phenytoin 50 mg tablet: chewable, 200	1	2	..	48.49	37.70	Dilantin Infatabs	PF
NP 1874P NP	phenytoin sodium 100 mg capsule, 200	1	2	..	30.46	31.61	Dilantin Sodium	PF
NP 1873N NP	phenytoin sodium 30 mg capsule, 200	1	2	..	29.52	30.67	Dilantin Sodium	PF

Succinimide derivatives

ETHOSUXIMIDE

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

NP 1413J NP	ethosuximide 250 mg capsule, 200	1	2	..	66.18	37.70	Zarontin	PF
NP 1414K NP	ethosuximide 250 mg/5 mL oral liquid, 200 mL	1	5	..	29.43	30.58	Zarontin	PF

Benzodiazepine derivatives

CLONAZEPAM

Restricted benefit

Epilepsy

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

NP 1807D NP	clonazepam 1 mg/mL injection [5 x 1 mL ampoules] (& inert substance diluent [5 x 1 mL ampoules], 1 pack	1	..	..	18.92	20.07	Rivotril	RO

CLONAZEPAM

Authority required

Neurologically proven epilepsy

Caution

Abuse of clonazepam has been reported. Refer to the current product information.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

NP 1806C NP	clonazepam 2 mg tablet, 100	2	2	..	*31.40	32.55	^a Paxam 2	AF
				^b 3.86	*35.26	32.55	^a Rivotril	RO
NP 1808E NP	clonazepam 2.5 mg/mL oral liquid, 10 mL	2	..	..	*15.38	16.53	Rivotril	RO

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
1805B NP	clonazepam 500 microgram tablet, 100	2	2	..	*19.84	20.99	^a Paxam 0.5	AF
				^B 3.42	*23.26	20.99	^a Rivotril	RO

NITRAZEPAM

Authority required

Myoclonic epilepsy

Authority required

Malignant neoplasia (late stage)

Authority required

For use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal

Authority required

For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2732T NP	nitrazepam 5 mg tablet, 25	2	5	..	*9.94	11.09	^a Alodorm	AF
				^B 2.48	*12.42	11.09	^a Mogadon	IA

Carboxamide derivatives

CARBAMAZEPINE

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2422L NP	CARBAMAZEPINE Tablet 100 mg, 100	2	2	..	*18.84	19.99	^a Carbamazepine Sandoz	SZ
				^B 2.96	*21.80	19.99	^a Tegretol 100	NV
5039F DP	CARBAMAZEPINE Tablet 100 mg, 100	2	..	..	*18.84	19.99	^a Carbamazepine Sandoz	SZ
				^B 2.96	*21.80	19.99	^a Tegretol 100	NV
5041H DP	carbamazepine 100 mg/5 mL oral liquid, 300 mL	‡1	..	..	21.69	22.84	Tegretol Liquid	NV
5038E DP	carbamazepine 200 mg tablet: modified release, 200 tablets	1	..	..	29.82	30.97	Tegretol CR 200	NV
5037D DP	carbamazepine 400 mg tablet: modified release, 200 tablets	1	..	..	49.37	37.70	Tegretol CR 400	NV

CARBAMAZEPINE

Note

For item codes 2419H and 1706T, pharmaceutical benefits that have the form tablet 200 mg are equivalent for the purposes of substitution.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1706T NP	CARBAMAZEPINE Tablet 200 mg, 100	2	2	..	*29.34	30.49	^a Carbamazepine Sandoz	SZ
				^B 2.96	*32.30	30.49	^a Tegretol 200	NV
2419H NP	carbamazepine 200 mg tablet, 200	1	2	..	29.33	30.48	^a Teril	AF

CARBAMAZEPINE

Note

For item codes 5040G and 1724R, pharmaceutical benefits that have the form tablet 200 mg are equivalent for the purposes of substitution.

1724R DP	CARBAMAZEPINE Tablet 200 mg, 100	2	..	..	*29.34	30.49	^a Carbamazepine Sandoz	SZ
				^B 2.96	*32.30	30.49	^a Tegretol 200	NV

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
5040G DP	carbamazepine 200 mg tablet, 200	1	..	..	29.33	30.48 ^a	Teril	AF

CARBAMAZEPINE

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2427R NP	carbamazepine 100 mg/5 mL oral liquid, 300 mL	\$1	5	..	21.69	22.84	Tegretol Liquid	NV
2426Q NP	carbamazepine 200 mg tablet: modified release, 200 tablets	1	2	..	29.82	30.97	Tegretol CR 200	NV
2431Y NP	carbamazepine 400 mg tablet: modified release, 200 tablets	1	2	..	49.37	37.70	Tegretol CR 400	NV

OXCARBAZEPINE

Authority required (STREAMLINED)

1587

Treatment of partial epileptic seizures and primary generalised tonic-clonic seizures, which are not controlled satisfactorily by other anti-epileptic drugs

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8584T NP	oxcarbazepine 150 mg tablet, 100	1	5	..	72.61	37.70	Trileptal	NV
8585W NP	oxcarbazepine 300 mg tablet, 100	1	5	..	115.42	37.70	Trileptal	NV
8588B NP	oxcarbazepine 60 mg/mL oral liquid, 250 mL	2	5	..	*138.46	37.70	Trileptal	NV
8586X NP	oxcarbazepine 600 mg tablet, 100	1	5	..	188.32	37.70	Trileptal	NV

Fatty acid derivatives

TIAGABINE

Authority required (STREAMLINED)

2664

Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8222R NP	tiagabine 10 mg tablet, 50	2	5	..	*139.18	37.70	Gabitril	OA
8223T NP	tiagabine 15 mg tablet, 50	2	5	..	*197.24	37.70	Gabitril	OA
8221Q NP	tiagabine 5 mg tablet, 50	2	5	..	*72.96	37.70	Gabitril	OA

VALPROATE

Caution

There are reports of fatal hepatotoxicity, particularly in children.

There is increasing evidence of dose-related teratogenesis from this drug.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2294R NP	valproate sodium 100 mg tablet, 100	2	2	..	*32.34	33.49	Epilim	SW
2289L NP	valproate sodium 200 mg tablet: enteric, 100	2	2	..	*22.58	23.73	^a Sodium Valproate Sandoz	SZ
							^a Valprease 200	QA
							^a Valpro 200	AF
							^a Valproate Winthrop EC	WA

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
				^B 1.70	*24.28	23.73	^a 200 Epilim EC	SW
2293Q NP	valproate sodium 200 mg/5 mL oral liquid, 300 mL	2	2	..	*38.92	37.70	Epilim Liquid	SW
2295T NP	valproate sodium 200 mg/5 mL oral liquid, 300 mL	2	2	..	*38.92	37.70	Epilim Syrup	SW
2290M NP	valproate sodium 500 mg tablet: enteric, 100	2	2	..	*38.08	37.70	^a Sodium Valproate Sandoz	SZ
							^a Valprease 500	QA
							^a Valpro 500	AF
							^a Valproate Winthrop EC 500	WA
				^B 1.96	*40.04	37.70	^a Epilim EC	SW

VIGABATRIN

Authority required (STREAMLINED)

1426

Treatment of epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs

Caution

Visual field defects have been reported with this drug.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2668K NP	vigabatrin 500 mg oral liquid: powder for, 60 x 500 mg sachets	1	5	..	79.48	37.70	Sabril	SW
2667J NP	vigabatrin 500 mg tablet, 100	1	5	..	119.11	37.70	Sabril	SW

Other antiepileptics

GABAPENTIN

Authority required (STREAMLINED)

2664

Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8505P NP	gabapentin 100 mg capsule, 100	1	5	..	12.95	14.10	^a APO-Gabapentin	TX
							^a Gabacor	NJ
							^a Gabapentin Aspen 100	FM
							^a Gabatine 100	QA
							^a Neurontin	PF
							^a Nupentin 100	AF
1834M NP	gabapentin 300 mg capsule, 100	1	5	..	27.43	28.58	^a Gabacor	NJ
							^a Gabapentin 300	CR
							^a Gabapentin Aspen 300	FM
							^a Gabapentin-GA	UA
							^a Gabapentin Sandoz	SZ
							^a Gabatine 300	QA
							^a Gantin	GN
							^a GenRx Gabapentin	GX
							^a Neurontin	PF
							^a Nupentin 300	AF
1835N NP	gabapentin 400 mg capsule, 100	1	5	..	34.94	36.09	^a Gabacor	NJ
							^a Gabapentin 400	CR
							^a Gabapentin Aspen 400	FM
							^a Gabapentin Sandoz	SZ
							^a Gabatine 400	QA
							^a Gantin	GN
							^a GenRx Gabapentin	GX

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
8559L NP	gabapentin 600 mg tablet, 100	1	5	..	50.16	37.70	a Neurontin	PF
							a Nupentin 400	AF
							a Gabapentin AN	EA
							a Gabapentin Aspen 600	FM
							a Gabaran	RA
							a Gabatine 600	QA
							a GenRx Gabapentin	GX
							a Neurontin	PF
							a Nupentin Tabs	AF
							a Pharmacor Gabapentin 600	CR
8389M NP	gabapentin 800 mg tablet, 100	1	5	..	63.81	37.70	a Gabapentin AN	EA
							a Gabapentin Aspen 800	FM
							a Gabaran	RA
							a Gabatine 800	QA
							a Gantin	GN
							a GenRx Gabapentin	GX
							a Neurontin	PF
							a Nupentin Tabs	AF
							a Pharmacor Gabapentin 800	CR

LACOSAMIDE

Authority required (STREAMLINED)

4271

Intractable partial epileptic seizures

Treatment Phase: Initial

Clinical criteria:

The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent,

AND

The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents,

AND

The treatment must be for dose titration purposes.

Population criteria:

Patient must be aged 16 years or older.

Treatment criteria:

Must be treated by a neurologist.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

9334G NP	lacosamide 100 mg tablet, 14	1	1	..	52.63	37.70	Vimpat	UC
9336J NP	lacosamide 150 mg tablet, 14	1	1	..	75.03	37.70	Vimpat	UC
9333F NP	lacosamide 50 mg tablet, 14	1	1	..	30.55	31.70	Vimpat	UC

LACOSAMIDE

Authority required (STREAMLINED)

4264

Intractable partial epileptic seizures

Treatment Phase: Initial

Clinical criteria:

The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent,

AND

The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	and at least two second-line adjunctive anti-epileptic agents.						
	Population criteria:						
	Patient must be aged 16 years or older.						
	Treatment criteria:						
	Must be treated by a neurologist.						
	<u>Authority required (STREAMLINED)</u>						
	4249						
	Intractable partial epileptic seizures						
	Treatment Phase: Continuing						
	Clinical criteria:						
	Patient must have previously been treated with PBS-subsidised lacosamide.						
	Population criteria:						
	Patient must be aged 16 years or older.						
	Note						
	Continuing Therapy Only:						
	For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.						
9335H NP	lacosamide 100 mg tablet, 56	1	5	..	188.80	37.70	Vimpat UC
	LACOSAMIDE						
	<u>Authority required (STREAMLINED)</u>						
	4240						
	Intractable partial epileptic seizures						
	Treatment Phase: Initial						
	Clinical criteria:						
	The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent,						
	AND						
	The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents.						
	Population criteria:						
	Patient must be aged 16 years or older.						
	Treatment criteria:						
	Must be treated by a neurologist.						
	<u>Authority required (STREAMLINED)</u>						
	4257						
	Intractable partial epileptic seizures						
	Treatment Phase: Continuing						
	Clinical criteria:						
	Patient must have previously been treated with PBS-subsidised lacosamide.						
	Population criteria:						
	Patient must be aged 16 years or older.						
	Note						
	No applications for increased maximum quantities will be authorised for the 56 tablet packs of the 150 mg and 200 mg strengths.						
	Note						
	Continuing Therapy Only:						
	For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.						
9337K NP	lacosamide 150 mg tablet, 56	1	5	..	273.00	37.70	Vimpat UC
9338L NP	lacosamide 200 mg tablet, 56	1	5	..	355.72	37.70	Vimpat UC

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
Treatment of epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs							
Note							
Continuing Therapy Only:							
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
2850B NP	lamotrigine 100 mg tablet, 56	1	5	..	34.31	35.46	a APO-Lamotrigine TX a GenRx Lamotrigine GX a Lamidus RA a Lamogine AF a Lamotrigine AN EA a Lamotrigine Aspen 100 FM a Lamotrigine-GA GN a Lamotrigine GQ generichealth a Lamotrigine Sandoz SZ a Lamotruster 100 CR a Reedos 100 DO a Seaze 100 QA a Torlemo DT 100 UA b2.67 36.98 35.46 a Lamictal AS a APO-Lamotrigine TX a GenRx Lamotrigine GX a Lamidus RA a Lamogine AF a Lamotrigine AN EA a Lamotrigine Aspen 200 FM a Lamotrigine-GA GN a Lamotrigine GQ generichealth a Lamotrigine Sandoz SZ a Lamotruster 200 CR a Reedos 200 DO a Seaze 200 QA a Torlemo DT 200 UA b2.32 53.84 37.70 a Lamictal AS a APO-Lamotrigine TX a GenRx Lamotrigine GX a Lamidus RA a Lamogine AF a Lamotrigine AN EA a Lamotrigine Aspen 25 FM a Lamotrigine-GA GN a Lamotrigine GQ generichealth a Lamotrigine Sandoz SZ a Lamotruster 25 CR a Reedos 25 DO a Seaze 25 QA a Torlemo DT 25 UA b2.89 19.56 17.82 a Lamictal AS a Lamogine AF a Lamotrigine Aspen 5 FM a Seaze 5 QA a Lamictal AS a APO-Lamotrigine TX a GenRx Lamotrigine GX a Lamidus RA a Lamogine AF a Lamotrigine AN EA
2851C NP	lamotrigine 200 mg tablet, 56	1	5	..	51.52	37.70	
2848X NP	lamotrigine 25 mg tablet, 56	1	5	..	16.67	17.82	
8063J NP	lamotrigine 5 mg tablet, 56	1	5	..	11.21	12.36	
2849Y NP	lamotrigine 50 mg tablet, 56	1	5	..	23.31	24.46	

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$		Brand Name and Manufacturer	
							a	Lamotrigine Aspen 50	FM
							a	Lamotrigine-GA	GN
							a	Lamotrigine generichealth	GQ
							a	Lamotrigine Sandoz	SZ
							a	Lamotrux 50	CR
							a	Reedos 50	DO
							a	Seaze 50	QA
							a	Torlemo DT 50	UA
				^B 2.55	25.86	24.46	a	Lamictal	AS
	LEVETIRACETAM								
	<u>Authority required (STREAMLINED)</u>								
	2664								
	Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs								
	Note								
	Continuing Therapy Only:								
	For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8656N	levetiracetam 1 g tablet, 60	1	5	..	76.03	37.70	a	APO-Levetiracetam	TX
NP							a	Chem mart Levetiracetam	CH
							a	Kepcet	GN
							a	Keppra	UC
							a	Kerron 1000	DO
							a	Kevtam	AF
							a	Levactam	ER
							a	Levecetam 1000	RZ
							a	Levetiracetam AN	EA
							a	Levetiracetam generichealth	GQ
							a	Levetiracetam SZ	SZ
							a	Levi 1000	FM
							a	Levitaccord	RA
							a	Levitam 1000	QA
							a	Terry White Chemists Levetiracetam	TW
8654L	levetiracetam 250 mg tablet, 60	1	5	..	32.84	33.99	a	APO-Levetiracetam	TX
NP							a	Chem mart Levetiracetam	CH
							a	Kepcet	GN
							a	Keppra	UC
							a	Kerron 250	DO
							a	Kevtam	AF
							a	Levactam	ER
							a	Levecetam 250	RZ
							a	Levetiracetam AN	EA
							a	Levetiracetam generichealth	GQ
							a	Levetiracetam SZ	SZ
							a	Levi 250	FM
							a	Levitaccord	RA
							a	Levitam 250	QA
							a	Terry White Chemists Levetiracetam	TW
8655M	levetiracetam 500 mg tablet, 60	1	5	..	49.05	37.70	a	APO-Levetiracetam	TX
NP							a	Chem mart Levetiracetam	CH
							a	Kepcet	GN
							a	Keppra	UC
							a	Kerron 500	DO
							a	Kevtam	AF

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							a Levactam	ER
							a Levecetam 500	RZ
							a Levetiracetam AN	EA
							a Levetiracetam generichealth	GQ
							a Levetiracetam SZ	SZ
							a Levi 500	FM
							a Levitaccord	RA
							a Levitam 500	QA
							a Terry White Chemists Levetiracetam	TW

LEVETIRACETAM

Authority required (STREAMLINED)

3291

Treatment of partial epileptic seizures, which are not controlled satisfactorily by other anti-epileptic drugs in a patient unable to take a solid dose form of levetiracetam

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

9169N NP	levetiracetam 100 mg/mL oral liquid, 300 mL	1	5	..	111.76	37.70	Keppra	UC

PERAMPANEL

Authority required (STREAMLINED)

4658

Intractable partial epileptic seizures

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

10151G NP	perampanel 10 mg tablet, 28	1	5	..	355.72	37.70	Fycompa	EI
10159Q NP	perampanel 12 mg tablet, 28	1	5	..	355.72	37.70	Fycompa	EI
10162W NP	perampanel 4 mg tablets, 28	1	5	..	188.80	37.70	Fycompa	EI
10163X NP	perampanel 6 mg tablet, 28	1	5	..	273.00	37.70	Fycompa	EI
10160R NP	perampanel 8 mg tablet, 28	1	5	..	355.72	37.70	Fycompa	EI

PERAMPANEL

Authority required (STREAMLINED)

4656

Intractable partial epileptic seizures

Treatment Phase: Initial

Clinical criteria:

The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent,

AND

The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents.

Treatment criteria:

Must be treated by a neurologist.

10157N	perampanel 2 mg tablet, 7	2	1	..	*52.64	37.70	Fycompa	EI

SULTHIAME

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2100M NP	sulthiame 200 mg tablet, 200	1	2	..	206.33	37.70	Ospolot	PL
2099L NP	sulthiame 50 mg tablet, 200	1	2	..	82.81	37.70	Ospolot	PL

TOPIRAMATE

Authority required (STREAMLINED)

2797

Treatment of partial epileptic seizures, primary generalised tonic-clonic epileptic seizures and seizures of the Lennox-Gastaut syndrome, which are not controlled satisfactorily by other anti-epileptic drugs

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8165R NP	topiramate 100 mg tablet, 60	1	5	..	47.17	37.70	^a APO-Topiramate	TX
							^a Epiramax 100	QA
							^a RBX Topiramate	RA
							^a Tamate	AF
							^a Topamax	JC
							^a Topiramate AN	EA
							^a Topiramate GH	GQ
							^a Topiramate Sandoz	SZ
8166T NP	topiramate 200 mg tablet, 60	1	5	..	73.13	37.70	^a APO-Topiramate	TX
							^a Epiramax 200	QA
							^a RBX Topiramate	RA
							^a Tamate	AF
							^a Topamax	JC
							^a Topiramate AN	EA
							^a Topiramate GH	GQ
							^a Topiramate Sandoz	SZ

TOPIRAMATE

Authority required (STREAMLINED)

2798

Treatment of partial epileptic seizures, primary generalised tonic-clonic epileptic seizures and seizures of the Lennox-Gastaut syndrome, which are not controlled satisfactorily by other anti-epileptic drugs in patients unable to take a solid dose form of topiramate

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8371N NP	topiramate 15 mg capsule, 60	1	5	..	18.40	19.55	Topamax Sprinkle	JC
8372P NP	topiramate 25 mg capsule, 60	1	5	..	22.49	23.64	Topamax Sprinkle	JC
8520K NP	topiramate 50 mg capsule, 60	1	5	..	32.98	34.13	Topamax Sprinkle	JC

TOPIRAMATE

Authority required (STREAMLINED)

2797

Treatment of partial epileptic seizures, primary generalised tonic-clonic epileptic seizures and seizures of the Lennox-Gastaut syndrome, which are not controlled satisfactorily by other anti-epileptic drugs

Authority required (STREAMLINED)

2799

Prophylaxis of migraine in a patient who has experienced an average of 3 or more migraines per month over a period of at least 6 months, and who:

- (a) has a contraindication to beta-blockers, as described in the relevant TGA-approved Product Information; OR
- (b) has experienced intolerance of a severity necessitating permanent withdrawal during treatment with a beta-blocker;

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	AND						
	(c) has a contraindication to pizotifen because the weight gain associated with this drug poses an unacceptable risk; OR						
	(d) has experienced intolerance of a severity necessitating permanent withdrawal during treatment with pizotifen.						
	Details of the contraindication and/or intolerance(s) must be documented in the patient's medical records when treatment is initiated						
	Note						
	Continuing Therapy Only:						
	For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.						
8163P NP	topiramate 25 mg tablet, 60	1	5	..	22.75	23.90	^a APO-Topiramate TX
							^a Epiramax 25 QA
							^a RBX Topiramate RA
							^a Tamate AF
							^a Topamax JC
							^a Topiramate AN EA
							^a Topiramate GH GQ
							^a Topiramate Sandoz SZ
8164Q NP	topiramate 50 mg tablet, 60	1	5	..	33.03	34.18	^a APO-Topiramate TX
							^a Epiramax 50 QA
							^a RBX Topiramate RA
							^a Tamate AF
							^a Topamax JC
							^a Topiramate AN EA
							^a Topiramate GH GQ
							^a Topiramate Sandoz SZ

ZONISAMIDE

Authority required (STREAMLINED)

2664

Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

9390F NP	zonisamide 100 mg capsule, 56	2	5	..	*93.80	37.70	Zonegran SA
9388D NP	zonisamide 25 mg capsule, 56	1	5	..	23.14	24.29	Zonegran SA
9389E NP	zonisamide 50 mg capsule, 56	1	5	..	34.06	35.21	Zonegran SA

ANTI-PARKINSON DRUGS

ANTICHOLINERGIC AGENTS

Tertiary amines

BENZHEXOL

1109J NP	benzhexol hydrochloride 2 mg tablet, 200	1	2	..	15.66	16.81	Artane QA
1110K NP	benzhexol hydrochloride 5 mg tablet, 200	1	1	..	22.35	23.50	Artane QA

BIPERIDEN

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2544X NP	biperiden hydrochloride 2 mg tablet, 100	2	2	..	*21.22	22.37	Akineton LM

Ethers of tropine or tropine derivatives

BENZTROPINE

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
2362H NP	benztropine mesylate 2 mg tablet, 60	1	2	..	15.47	16.62	Benzotrop	PL
3038X NP	benztropine mesylate 2 mg/2 mL injection, 5 x 2 mL ampoules	1	..	..	103.93	37.70	Cogentin	FK
5031T DP	benztropine mesylate 2 mg/2 mL injection, 5 x 2 mL ampoules	1	..	..	103.93	37.70	Cogentin	FK

DOPAMINERGIC AGENTS

Dopa and dopa derivatives

LEVODOPA + BENSERAZIDE

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8219N NP	LEVODOPA with BENSERAZIDE Dispersible tablet 100 mg-25 mg, 100	1	5	..	39.26	37.70	Madopar Rapid 125	RO
8218M NP	LEVODOPA with BENSERAZIDE Dispersible tablet 50 mg-12.5 mg, 100	1	5	..	23.34	24.49	Madopar Rapid 62.5	RO
2225D NP	levodopa 100 mg + benserazide 25 mg capsule, 100	1	5	..	39.26	37.70	Madopar 125	RO
2231K NP	levodopa 100 mg + benserazide 25 mg capsule: modified release, 100 capsules	1	5	..	42.34	37.70	Madopar HBS	RO
2229H NP	levodopa 100 mg + benserazide 25 mg tablet, 100	1	5	..	39.26	37.70	Madopar 125	RO
2226E NP	levodopa 200 mg + benserazide 50 mg capsule, 100	1	5	..	50.35	37.70	Madopar	RO
2228G NP	levodopa 200 mg + benserazide 50 mg tablet, 100	1	5	..	50.35	37.70	Madopar	RO
2227F NP	levodopa 50 mg + benserazide 12.5 mg capsule, 100	1	5	..	23.34	24.49	Madopar 62.5	RO

LEVODOPA + CARBIDOPA ANHYDROUS

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1242J NP	levodopa 100 mg + carbidopa anhydrous 25 mg tablet, 100	1	5	..	38.63	37.70	^a Kinson	AF
				^b 5.19	43.82	37.70	^a Sinemet 100/25	MK
1245M NP	levodopa 250 mg + carbidopa anhydrous 25 mg tablet, 100	1	5	..	45.43	37.70	Sinemet	MK

LEVODOPA + CARBIDOPA ANHYDROUS

Authority required

Maintenance therapy following treatment which was commenced in a hospital-based movement disorder clinic, of a patient with advanced Parkinson disease with severe disabling motor fluctuations not adequately controlled by oral therapy

Note

Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8970D NP	levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL gel: intestinal, 7 x 100 mL bags	8	5	..	*11682.68	37.70	Duodopa	VE

LEVODOPA + CARBIDOPA ANHYDROUS

Authority required (STREAMLINED)

1257

Parkinson's disease where fluctuations in motor function are not adequately controlled by frequent dosing with conventional formulations of levodopa with decarboxylase inhibitor

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
1255C NP	levodopa 200 mg + carbidopa anhydrous 50 mg tablet: modified release, 100 tablets	1	5	..	68.21	37.70	Sinemet CR	MK
LEVODOPA + CARBIDOPA ANHYDROUS + ENTACAPONE								
<u>Authority required (STREAMLINED)</u>								
3305								
Parkinson disease in patients being treated with levodopa—decarboxylase inhibitor combinations who are experiencing fluctuations in motor function due to end-of-dose effect								
<u>Authority required (STREAMLINED)</u>								
3306								
Parkinson disease in patients stabilised on concomitant treatment with levodopa—decarboxylase inhibitor combinations and entacapone								
<u>Note</u>								
Continuing Therapy Only:								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8798C NP	levodopa 100 mg + carbidopa anhydrous 25 mg + entacapone 200 mg tablet, 100	2	4	..	*342.26	37.70	Stalevo 100/25/200mg	NV
9345W NP	levodopa 125 mg + carbidopa anhydrous 31.25 mg + entacapone 200 mg tablet, 100	2	4	..	*354.30	37.70	Stalevo 125/31.25/200mg	NV
8799D NP	levodopa 150 mg + carbidopa anhydrous 37.5 mg + entacapone 200 mg tablet, 100	2	4	..	*372.30	37.70	Stalevo 150/37.5/200mg	NV
9292C NP	levodopa 200 mg + carbidopa anhydrous 50 mg + entacapone 200 mg tablet, 100	2	4	..	*399.96	37.70	Stalevo 200/50/200mg	NV
8797B NP	levodopa 50 mg + carbidopa anhydrous 12.5 mg + entacapone 200 mg tablet, 100	2	4	..	*312.22	37.70	Stalevo 50/12.5/200mg	NV
9344T NP	levodopa 75 mg + carbidopa anhydrous 18.75 mg + entacapone 200 mg tablet, 100	2	4	..	*325.46	37.70	Stalevo 75/18.75/200mg	NV

Adamantane derivatives

AMANTADINE

Restricted benefit

Parkinson's disease which is not drug induced

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

3016R NP	amantadine hydrochloride 100 mg capsule, 100	1	5	..	44.64	37.70	Symmetrel 100	NV

Dopamine agonists

BROMOCRIPTINE

Restricted benefit

Acromegaly

Restricted benefit

Parkinson's disease

Restricted benefit

Pathological hyperprolactinaemia where surgery is not indicated

Restricted benefit

Pathological hyperprolactinaemia where surgery has already been used with incomplete resolution

Restricted benefit

Pathological hyperprolactinaemia where radiotherapy is not indicated

Restricted benefit

Pathological hyperprolactinaemia where radiotherapy has already been used with incomplete resolution

Note

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.								
Note								
For item codes 1443Y and 1559C, pharmaceutical benefits that have the form tablet 2.5 mg (base) are equivalent for the purposes of substitution.								
1443Y	bromocriptine 2.5 mg tablet, 30	2	5	..	*31.76	32.91	^a Parlodel	NV
1559C	bromocriptine 2.5 mg tablet, 60	1	5	..	31.76	32.91	^a Krypton 2.5	AF
CABERGOLINE								
Restricted benefit								
Parkinson's disease								
Note								
Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.								
Note								
Continuing Therapy Only:								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8393R NP	cabergoline 1 mg tablet, 30	1	5	..	60.12	37.70	^a Cabaser	PF
8394T NP	cabergoline 2 mg tablet, 30	1	5	..	78.28	37.70	^a Cobasol	GN
							^a Cabaser	PF
							^a Cobasol	GN
PRAMIPEXOLE								
Restricted benefit								
Parkinson disease								
Caution								
Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.								
Note								
Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.								
Note								
Continuing Therapy Only:								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
9153R NP	pramipexole hydrochloride monohydrate 1 mg tablet, 100	1	5	..	129.16	37.70	^a APO-Pramipexole	TX
9151P NP	pramipexole hydrochloride monohydrate 125 microgram tablet, 30	1	..	..	11.23	12.38	^a Pramipexole AN	EA
							^a Pramipexole GH	GQ
							^a Sifrol	BY
							^a Simipex 1	QA
							^a Simpral	AF
							^a APO-Pramipexole	TX
							^a Pramipexole AN	EA
							^a Pramipexole GH	GQ
							^a Sifrol	BY
							^a Simipex 0.125	QA
9152Q NP	pramipexole hydrochloride monohydrate 250 microgram tablet, 100	1	5	..	36.07	37.22	^a Simpral	AF
							^a APO-Pramipexole	TX
							^a Pramipexole AN	EA
							^a Pramipexole GH	GQ
							^a Sifrol	BY
							^a Simipex 0.25	QA
^a Simpral	AF							

PRAMIPEXOLE
Restricted benefit
 Parkinson disease

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
Caution								
Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.								
Note								
Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.								
Note								
No applications for increased maximum quantities and/or repeats will be approved for extended release pramipexole formulations.								
Note								
Continuing Therapy Only:								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
3420B NP	pramipexole hydrochloride monohydrate 1.5 mg tablet: modified release, 30 tablets	1	5	..	57.24	37.70	Sifrol ER	BY
5143Q NP	pramipexole hydrochloride monohydrate 2.25 mg tablet: modified release, 30 tablets	1	5	..	82.50	37.70	Sifrol ER	BY
3421C NP	pramipexole hydrochloride monohydrate 3 mg tablet: modified release, 30 tablets	1	5	..	116.91	37.70	Sifrol ER	BY
5145T NP	pramipexole hydrochloride monohydrate 3.75 mg tablet: modified release, 30 tablets	1	5	..	142.16	37.70	Sifrol ER	BY
3418X NP	pramipexole hydrochloride monohydrate 375 microgram tablet: modified release, 30 tablets	1	5	..	20.18	21.33	Sifrol ER	BY
3422D NP	pramipexole hydrochloride monohydrate 4.5 mg tablet: modified release, 30 tablets	1	5	..	172.00	37.70	Sifrol ER	BY
3419Y NP	pramipexole hydrochloride monohydrate 750 microgram tablet: modified release, 30 tablets	1	5	..	33.14	34.29	Sifrol ER	BY

PRAMIPEXOLE

Restricted benefit

Treatment of severe primary Restless Legs Syndrome in a patient who manifests all 4 diagnostic criteria below and whose baseline International Restless Legs Syndrome Rating Scale (IRLSRS) score is greater than or equal to 21 points prior to initiation of pramipexole.

The date and IRLSRS score must be documented in the patient's medical records at the time pramipexole treatment is initiated.

The diagnostic criteria for Restless Legs Syndrome are:

- (a) An urge to move the legs usually accompanied or caused by unpleasant sensations in the legs; and
- (b) The urge to move or unpleasant sensations begin or worsen during periods of rest or inactivity such as lying or sitting; and
- (c) The urge to move or unpleasant sensations are partially or totally relieved by movement, such as walking or stretching, at least as long as the activity continues; and
- (d) The urge to move or unpleasant sensations are worse in the evening or night than during the day or only occur during the evening or night.

Pramipexole is not PBS-subsidised for Restless Legs Syndrome secondary to other causes

Caution

Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.

Note

Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

9393J NP	pramipexole hydrochloride monohydrate 125 microgram tablet, 30	1	2	..	11.23	12.38	Sifrol	BY
9394K NP	pramipexole hydrochloride monohydrate 250 microgram tablet, 100	1	2	..	36.07	37.22	Sifrol	BY

ROTIGOTINE

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	<u>Restricted benefit</u>							
	Parkinson disease							
	Clinical criteria:							
	The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.							
2385M	rotigotine 2 mg/24 hours patch, 28	1	5	..	77.59	37.70	Neupro	UC
	ROTIGOTINE							
	<u>Restricted benefit</u>							
	Parkinson disease							
	Clinical criteria:							
	The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.							
2384L	rotigotine 4 mg/24 hours patch, 28	1	5	..	101.20	37.70	Neupro	UC
2410W	rotigotine 6 mg/24 hours patch, 28	1	5	..	113.92	37.70	Neupro	UC

Monoamine oxidase B inhibitors

RASAGILINE

Authority required (STREAMLINED)

4053

Parkinson disease

Note

No applications for increased maximum quantities and/or repeats will be authorised.

1952R NP	RASAGILINE Tablet 1 mg (as mesilate), 30	1	5	..	121.93	37.70	Azilect	LU

SELEGILINE

Restricted benefit

Late stage Parkinson's disease as adjunctive therapy in patients being treated with levodopa—decarboxylase inhibitor combinations

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1973W NP	selegiline hydrochloride 5 mg tablet, 100	1	5	..	53.30	37.70	^a Eldepryl	AS
							^a Selgene	AF

Other dopaminergic agents

ENTACAPONE

Authority required (STREAMLINED)

2067

Parkinson's disease as adjunctive therapy in patients being treated with levodopa—decarboxylase inhibitor combinations who are experiencing fluctuations in motor function due to end-of-dose effect

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8367J NP	entacapone 200 mg tablet, 100	2	4	..	*282.16	37.70	Comtan	NV

PSYCHOLEPTICS

ANTIPSYCHOTICS

Phenothiazines with aliphatic side-chain

CHLORPROMAZINE

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
1196Y NP	chlorpromazine hydrochloride 10 mg tablet, 100	1	5	..	11.21	12.36	Largactil	SW
1199D NP	chlorpromazine hydrochloride 100 mg tablet, 100	1	5	..	17.78	18.93	Largactil	SW
1197B NP	chlorpromazine hydrochloride 25 mg tablet, 100	1	5	..	11.83	12.98	Largactil	SW
1201F NP	chlorpromazine hydrochloride 5 mg/mL oral liquid, 100 mL	1	5	..	13.13	14.28	Largactil	SW
1195X NP	chlorpromazine hydrochloride 50 mg/2 mL injection, 10 x 2 mL ampoules	1	..	..	20.82	21.97	Largactil	SW

Phenothiazines with piperazine structure

FLUPHENAZINE DECANOATE

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1046C NP	fluphenazine decanoate 12.5 mg/0.5 mL injection, 5 x 0.5 mL ampoules	1	..	..	19.56	20.71	Modecate	BQ
3098C NP	fluphenazine decanoate 25 mg/mL injection, 5 x 1 mL ampoules	1	..	..	26.72	27.87	Modecate	BQ
1001Q NP	fluphenazine decanoate 50 mg/2 mL injection, 5 x 2 mL ampoules	1	..	..	37.99	37.70	Modecate	BQ

TRIFLUOPERAZINE

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2185B NP	trifluoperazine 1 mg tablet, 100	1	5	..	16.85	18.00	Stelazine	GH
2386N NP	trifluoperazine 2 mg tablet, 100	1	5	..	21.78	22.93	Stelazine	GH
2186C NP	trifluoperazine 5 mg tablet, 100	1	5	..	23.86	25.01	Stelazine	GH

Phenothiazines with piperidine structure

PERICYAZINE

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

3053Q NP	pericyazine 10 mg tablet, 100	1	5	..	15.53	16.68	Neulactil	SW
3052P NP	pericyazine 2.5 mg tablet, 100	1	5	..	11.03	12.18	Neulactil	SW

Butyrophenone derivatives

HALOPERIDOL

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2767P NP	haloperidol 1.5 mg tablet, 100	1	5	..	11.25	12.40	Serenace	QA
2763K NP	haloperidol 2 mg/mL oral liquid, 100 mL	1	5	..	20.79	21.94	Serenace	QA
2770T NP	haloperidol 5 mg tablet, 50	1	5	..	11.02	12.17	Serenace	QA
2768Q NP	haloperidol 5 mg/mL injection, 10 x 1 mL ampoules	1	..	..	22.62	23.77	Serenace	QA
2761H NP	haloperidol 500 microgram tablet, 100	1	5	..	10.90	12.05	Serenace	QA

HALOPERIDOL DECANOATE

Note

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
Shared Care Model:								
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
2766N NP	haloperidol (as decanoate) 150 mg/3 mL injection, 5 x 3 mL ampoules	1	..	..	51.87	37.70	Haldol decanoate	JC
2765M NP	haloperidol (as decanoate) 50 mg/mL injection, 5 x 1 mL vials	1	..	..	30.06	31.21	Haldol decanoate	JC

Indole derivatives

ZIPRASIDONE

Authority required (STREAMLINED)

1589

Schizophrenia

Authority required (STREAMLINED)

3084

Monotherapy, for up to 6 months, of an episode of acute mania or mixed episodes associated with bipolar I disorder

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

9070J NP	ziprasidone 20 mg capsule, 60	1	5	..	66.05	37.70	^a APO-Ziprasidone	TX
							^a Zeldox	PF
9071K NP	ziprasidone 40 mg capsule, 60	1	5	..	125.54	37.70	^a APO-Ziprasidone	TX
							^a Zeldox	PF
9072L NP	ziprasidone 60 mg capsule, 60	1	5	..	184.30	37.70	^a APO-Ziprasidone	TX
							^a Zeldox	PF
9073M NP	ziprasidone 80 mg capsule, 60	1	5	..	240.24	37.70	^a APO-Ziprasidone	TX
							^a Zeldox	PF

Thioxanthene derivatives

FLUPENTHIXOL DECANOATE

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2257T NP	flupenthixol decanoate 100 mg/mL injection, 5 x 1 mL ampoules	1	..	..	48.61	37.70	Fluanxol Concentrated Depot	LU
2255Q NP	flupenthixol decanoate 20 mg/mL injection, 5 x 1 mL ampoules	1	..	..	20.85	22.00	Fluanxol Depot	LU

ZUCLOPENTHIXOL DECANOATE

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8097E NP	zuclopenthixol decanoate 200 mg/mL injection, 5 x 1 mL ampoules	1	..	..	27.58	28.73	Clopixol Depot	LU

Diazepines, oxazepines, thiazepines and oxepines

ASENAPINE

Authority required (STREAMLINED)

1589

Schizophrenia

Authority required (STREAMLINED)

3935

Treatment, for up to 6 months, of an episode of acute mania or mixed episodes associated with bipolar I disorder

Authority required (STREAMLINED)

3936

Maintenance treatment, as monotherapy, of bipolar I disorder

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
Note								
Shared Care Model:								
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
5141N NP	asenapine 10 mg wafer: sublingual, 60 wafers	1	5	..	253.06	37.70	Saphris	LU
5140M NP	asenapine 5 mg wafer: sublingual, 60 wafers	1	5	..	157.41	37.70	Saphris	LU
OLANZAPINE								
Authority required (STREAMLINED)								
1589								
Schizophrenia								
Authority required (STREAMLINED)								
2044								
Maintenance treatment of bipolar I disorder								
Note								
Pharmaceutical benefits that have the form olanzapine tablet 10 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 10 mg are equivalent for the purposes of substitution.								
3382B NP	OLANZAPINE Tablet 10 mg (orally disintegrating), 28	1	5	..	47.56	37.70	^a APO-Olanzapine ODT	TX
							^a Chem mart Olanzapine ODT	CH
							^a Olanzapine AN ODT	EA
							^a Olanzapine-GA ODT	GN
							^a Olanzapine ODT-DRLA	RZ
							^a Olanzapine ODT generichealth 10	GQ
							^a Olanzapine RBX ODT	RA
							^a Olanzapine Sandoz ODT 10	SZ
							^a Pharmacy Choice Olanzapine ODT	RI
							^a Terry White Chemists Olanzapine ODT	TW
OLANZAPINE								
Authority required (STREAMLINED)								
1589								
Schizophrenia								
Authority required (STREAMLINED)								
2044								
Maintenance treatment of bipolar I disorder								
Note								
Pharmaceutical benefits that have the form olanzapine tablet 5 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 5 mg are equivalent for the purposes of substitution.								
3381Y NP	OLANZAPINE Tablet 5 mg (orally disintegrating), 28	1	5	..	27.43	28.58	^a APO-Olanzapine ODT	TX
							^a Chem mart Olanzapine ODT	CH
							^a Olanzapine AN ODT	EA
							^a Olanzapine-GA ODT	GN
							^a Olanzapine ODT-DRLA	RZ
							^a Olanzapine ODT generichealth 5	GQ
							^a Olanzapine RBX ODT	RA
							^a Olanzapine Sandoz ODT 5	SZ
							^a Pharmacy Choice Olanzapine ODT	RI
							^a Terry White Chemists Olanzapine ODT	TW
OLANZAPINE								
Authority required (STREAMLINED)								

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	1589 Schizophrenia <u>Authority required (STREAMLINED)</u> 2044 Maintenance treatment of bipolar I disorder <u>Note</u> Pharmaceutical benefits that have the form olanzapine tablet 10 mg and pharmaceutical benefits that have the form olanzapine tablet 10 mg (as benzoate) are equivalent for the purposes of substitution.						
1042W NP	olanzapine 10 mg tablet, 28	1	5	..	47.56	37.70	^a Olanzapine generichealth 10 GQ
	OLANZAPINE <u>Authority required (STREAMLINED)</u> 1589 Schizophrenia <u>Authority required (STREAMLINED)</u> 2044 Maintenance treatment of bipolar I disorder <u>Note</u> Pharmaceutical benefits that have the form olanzapine tablet 10 mg and pharmaceutical benefits that have the form olanzapine tablet 10 mg (as benzoate) are equivalent for the purposes of substitution. <u>Note</u> Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.						
8187X NP	olanzapine 10 mg tablet, 28	1	5	..	47.56	37.70	^a APO-Olanzapine TX ^a Chem mart Olanzapine CH ^a Lanzek EL ^a Olanzapine AN EA ^a Olanzapine-DRLA RZ ^a Olanzapine-GA GN ^a Olanzapine GH GQ ^a Olanzapine RBX RA ^a Olanzapine Sandoz SZ ^a Ozin 10 DO ^a Pharmacor Olanzapine 10 CR ^a Pharmacy Choice Olanzapine RI ^a Terry White Chemists Olanzapine TW ^a Zypine AF ^a Zyprexa LY
	OLANZAPINE <u>Authority required (STREAMLINED)</u> 1589 Schizophrenia <u>Authority required (STREAMLINED)</u> 2044 Maintenance treatment of bipolar I disorder <u>Note</u> Pharmaceutical benefits that have the form olanzapine tablet 10 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 10 mg are equivalent for the purposes of substitution. <u>Note</u> Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.						
8434X NP	olanzapine 10 mg wafer, 28	1	5	..	47.56	37.70	^a Lanzek Zydys EL ^a Zypine ODT AF

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							^a Zyprexa Zydis	LY
	OLANZAPINE <u>Authority required (STREAMLINED)</u> 1589 Schizophrenia <u>Authority required (STREAMLINED)</u> 2044 Maintenance treatment of bipolar I disorder <u>Note</u> Pharmaceutical benefits that have the form olanzapine tablet 15 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 15 mg are equivalent for the purposes of substitution.							
3384D NP	olanzapine 15 mg tablet, 28	1	5	..	66.64	37.70	^a APO-Olanzapine ODT	TX
							^a Chem mart Olanzapine ODT	CH
							^a Olanzapine AN ODT	EA
							^a Terry White Chemists Olanzapine ODT	TW
	OLANZAPINE <u>Authority required (STREAMLINED)</u> 1589 Schizophrenia <u>Authority required (STREAMLINED)</u> 2044 Maintenance treatment of bipolar I disorder <u>Note</u> Pharmaceutical benefits that have the form olanzapine tablet 15 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 15 mg are equivalent for the purposes of substitution.							
	<u>Note</u> Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
8952E NP	olanzapine 15 mg wafer, 28	1	5	..	66.64	37.70	^a Zypine ODT	AF
							^a Zyprexa Zydis	LY
	OLANZAPINE <u>Authority required (STREAMLINED)</u> 1589 Schizophrenia <u>Authority required (STREAMLINED)</u> 2044 Maintenance treatment of bipolar I disorder							
	<u>Note</u> Pharmaceutical benefits that have the form olanzapine tablet 2.5 mg and pharmaceutical benefits that have the form olanzapine tablet 2.5 mg (as benzoate) are equivalent for the purposes of substitution.							
1024X NP	olanzapine 2.5 mg tablet, 28	1	5	..	17.19	18.34	^a Olanzapine generichealth 2.5	GQ
	OLANZAPINE <u>Authority required (STREAMLINED)</u> 1589 Schizophrenia <u>Authority required (STREAMLINED)</u> 2044 Maintenance treatment of bipolar I disorder <u>Note</u> Pharmaceutical benefits that have the form olanzapine tablet 2.5 mg and pharmaceutical benefits that have the form olanzapine tablet 2.5 mg (as benzoate) are equivalent for the purposes of substitution.							
	<u>Note</u>							

OLANZAPINE
Authority required (STREAMLINED)
4304
Schizophrenia
Caution

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Monitor for post-injection syndrome for at least two hours after each injection.							
	Note							
	Special Pricing Arrangements apply.							
	Note							
	Shared Care Model:							
	For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
9294E NP	olanzapine 210 mg injection: modified release [1 x 210 mg vial] (&) inert substance diluent [1 x 3 mL vial], 1 pack	2	5	..	*500.12	37.70	Zyprexa Relprevv	LY
9295F NP	olanzapine 300 mg injection: modified release [1 x 300 mg vial] (&) inert substance diluent [1 x 3 mL vial], 1 pack	2	5	..	*809.60	37.70	Zyprexa Relprevv	LY
9303P NP	olanzapine 405 mg injection: modified release [1 x 405 mg vial] (&) inert substance diluent [1 x 3 mL vial], 1 pack	1	5	..	500.12	37.70	Zyprexa Relprevv	LY
	OLANZAPINE							
	Authority required (STREAMLINED)							
	1589							
	Schizophrenia							
	Authority required (STREAMLINED)							
	2044							
	Maintenance treatment of bipolar I disorder							
	Note							
	Pharmaceutical benefits that have the form olanzapine tablet 5 mg and pharmaceutical benefits that have the form olanzapine tablet 5 mg (as benzoate) are equivalent for the purposes of substitution.							
1037N NP	olanzapine 5 mg tablet, 28	1	5	..	27.43	28.58	^a Olanzapine generichealth 5	GQ
	OLANZAPINE							
	Authority required (STREAMLINED)							
	1589							
	Schizophrenia							
	Authority required (STREAMLINED)							
	2044							
	Maintenance treatment of bipolar I disorder							
	Note							
	Pharmaceutical benefits that have the form olanzapine tablet 5 mg and pharmaceutical benefits that have the form olanzapine tablet 5 mg (as benzoate) are equivalent for the purposes of substitution.							
	Note							
	Shared Care Model:							
	For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
8185T NP	olanzapine 5 mg tablet, 28	1	5	..	27.43	28.58	^a APO-Olanzapine	TX
							^a Chem mart Olanzapine	CH
							^a Lanzek	EL
							^a Olanzapine AN	EA
							^a Olanzapine-DRLA	RZ
							^a Olanzapine-GA	GN
							^a Olanzapine GH	GQ
							^a Olanzapine RBX	RA
							^a Olanzapine Sandoz	SZ
							^a Ozin 5	DO
							^a Pharmacor Olanzapine 5	CR
							^a Pharmacy Choice Olanzapine	RI
							^a Terry White Chemists	TW

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							Olanzapine	
							^a Zypine	AF
							^a Zyprex	LY
OLANZAPINE								
<u>Authority required (STREAMLINED)</u>								
1589								
Schizophrenia								
<u>Authority required (STREAMLINED)</u>								
2044								
Maintenance treatment of bipolar I disorder								
<u>Note</u>								
Pharmaceutical benefits that have the form olanzapine tablet 5 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 5 mg are equivalent for the purposes of substitution.								
<u>Note</u>								
Shared Care Model:								
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8433W NP	olanzapine 5 mg wafer, 28	1	5	..	27.43	28.58	^a Lanzek Zydis	EL
							^a Zypine ODT	AF
							^a Zyprex Zydis	LY
OLANZAPINE								
<u>Authority required (STREAMLINED)</u>								
1589								
Schizophrenia								
<u>Authority required (STREAMLINED)</u>								
2044								
Maintenance treatment of bipolar I disorder								
<u>Note</u>								
Pharmaceutical benefits that have the form olanzapine tablet 7.5 mg and pharmaceutical benefits that have the form olanzapine tablet 7.5 mg (as benzoate) are equivalent for the purposes of substitution.								
1041T NP	olanzapine 7.5 mg tablet, 28	1	5	..	38.06	37.70	^a Olanzapine generichealth 7.5	GQ
OLANZAPINE								
<u>Authority required (STREAMLINED)</u>								
1589								
Schizophrenia								
<u>Authority required (STREAMLINED)</u>								
2044								
Maintenance treatment of bipolar I disorder								
<u>Note</u>								
Pharmaceutical benefits that have the form olanzapine tablet 7.5 mg and pharmaceutical benefits that have the form olanzapine tablet 7.5 mg (as benzoate) are equivalent for the purposes of substitution.								
<u>Note</u>								
Shared Care Model:								
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8186W NP	olanzapine 7.5 mg tablet, 28	1	5	..	38.06	37.70	^a APO-Olanzapine	TX
							^a Chem mart Olanzapine	CH
							^a Lanzek	EL
							^a Olanzapine AN	EA
							^a Olanzapine-DRLA	RZ
							^a Olanzapine-GA	GN
							^a Olanzapine GH	GQ
							^a Olanzapine RBX	RA
							^a Olanzapine Sandoz	SZ
							^a Ozin 7.5	DO
							^a Pharmacor Olanzapine	CR

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							7.5	
							a Pharmacy Choice Olanzapine	RI
							a Terry White Chemists Olanzapine	TW
							a Zypine	AF
							a Zyprexa	LY
QUETIAPINE								
<u>Authority required (STREAMLINED)</u>								
1589								
Schizophrenia								
<u>Authority required (STREAMLINED)</u>								
2765								
Monotherapy, for up to 6 months, of an episode of acute mania associated with bipolar I disorder								
<u>Authority required (STREAMLINED)</u>								
2044								
Maintenance treatment of bipolar I disorder								
<u>Note</u>								
Shared Care Model:								
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8457D NP	quetiapine 100 mg tablet, 90	1	5	..	59.99	37.70	a APO-Quetiapine	TX
							a Chem mart Quetiapine	CH
							a Delucon 100	DO
							a Kaptan	ER
							a Pharmacor Quetiapine 100	CR
							a Pharmacy Choice Quetiapine	RI
							a Quetia 100	FM
							a Quetiaccord	UA
							a Quetiapine Actavis 100	VN
							a Quetiapine AN	EA
							a Quetiapine-DRLA	RZ
							a Quetiapine-GA	GN
							a Quetiapine GH 100	GQ
							a Quetiapine RBX	RA
							a Quetiapine Sandoz	SZ
							a Seronia 100	QA
							a Seroquel	AP
							a Syquet	AF
							a Terry White Chemists Quetiapine	TW
5458G NP	quetiapine 150 mg tablet: modified release, 60 tablets	1	5	..	59.99	37.70	Seroquel XR	AP
8458E NP	quetiapine 200 mg tablet, 60	1	5	..	79.29	37.70	a APO-Quetiapine	TX
							a Chem mart Quetiapine	CH
							a Delucon 200	DO
							a Kaptan	ER
							a Pharmacor Quetiapine 200	CR
							a Pharmacy Choice Quetiapine	RI
							a Quetia 200	FM
							a Quetiaccord	UA
							a Quetiapine Actavis 200	VN
							a Quetiapine AN	EA
							a Quetiapine-DRLA	RZ
							a Quetiapine-GA	GN
							a Quetiapine GH 200	GQ
							a Quetiapine RBX	RA

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							a Quetiapine Sandoz	SZ
							a Seronia 200	QA
							a Seroquel	AP
							a Syquet	AF
							a Terry White Chemists	TW
9203J	quetiapine 200 mg tablet: modified release, 60 tablets	1	5	..	79.29	37.70	Quetiapine Seroquel XR	AP
NP								
8580N	quetiapine 300 mg tablet, 60	1	5	..	113.20	37.70	a APO-Quetiapine	TX
NP								
							a Chem mart Quetiapine	CH
							a Delucon 300	DO
							a Kaptan	ER
							a Pharmacor Quetiapine 300	CR
							a Pharmacy Choice	RI
							Quetiapine	
							a Quetia 300	FM
							a Quetiaccord	UA
							a Quetiapine Actavis 300	VN
							a Quetiapine AN	EA
							a Quetiapine-DRLA	RZ
							a Quetiapine-GA	GN
							a Quetiapine GH 300	GQ
							a Quetiapine RBX	RA
							a Quetiapine Sandoz	SZ
							a Seronia 300	QA
							a Seroquel	AP
							a Syquet	AF
							a Terry White Chemists	TW
							Quetiapine Seroquel XR	AP
9204K	quetiapine 300 mg tablet: modified release, 60 tablets	1	5	..	113.20	37.70		AP
NP								
9205L	quetiapine 400 mg tablet: modified release, 60 tablets	1	5	..	151.84	37.70	Seroquel XR	AP
NP								
9202H	quetiapine 50 mg tablet: modified release, 60 tablets	1	5	..	45.46	37.70	Seroquel XR	AP
NP								

QUETIAPINE

Authority required (STREAMLINED)

4391

Schizophrenia

Clinical criteria:

The treatment must be for dose titration purposes.

Authority required (STREAMLINED)

4396

Acute mania

Clinical criteria:

The condition must be associated with bipolar I disorder,

AND

The treatment must be as monotherapy,

AND

The treatment must be for dose titration purposes.

Authority required (STREAMLINED)

4385

Bipolar I disorder

Clinical criteria:

The treatment must be maintenance therapy,

AND

The treatment must be for dose titration purposes.

Note

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
No increase in the maximum quantity or number of units may be authorised.							
Note							
No increase in the maximum number of repeats may be authorised.							
Note							
Shared Care Model:							
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
8456C NP	quetiapine 25 mg tablet, 60	1	..	..	26.44	27.59	a APO-Quetiapine TX a Chem mart Quetiapine CH a Delucon 25 DO a Kaptan ER a Pharmacor Quetiapine 25 CR a Pharmacy Choice Quetiapine RI a Quetia 25 FM a Quetiaccord UA a Quetiapine Actavis 25 VN a Quetiapine AN EA a Quetiapine-DRLA RZ a Quetiapine-GA GN a Quetiapine GH 25 GQ a Quetiapine RBX RA a Quetiapine Sandoz SZ a Seronia 25 QA a Seroquel AP a Syquet AF a Terry White Chemists Quetiapine TW

Benzamides

AMISULPRIDE

Authority required (STREAMLINED)

1589

Schizophrenia

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8594H NP	amisulpride 100 mg tablet, 30	1	5	..	19.21	20.36	a Amisulpride 100 Winthrop WA a Amisulpride Sandoz SZ a APO-Amisulpride TX a Solian 100 SW a Sulprix AF Solian Solution SW
8736T NP	amisulpride 100 mg/mL oral liquid, 60 mL	2	5	..	*149.08	37.70	Solian Solution SW
8595J NP	amisulpride 200 mg tablet, 60	1	5	..	58.03	37.70	a Amisulpride 200 Winthrop WA a Amisulpride Sandoz SZ a APO-Amisulpride TX a Solian 200 SW a Sulprix AF a Amipride 400 QA
8596K NP	amisulpride 400 mg tablet, 60	1	5	..	99.73	37.70	a Amisulpride 400 Winthrop WA a Amisulpride Sandoz SZ a APO-Amisulpride TX a Solian 400 SW a Sulprix AF

Other antipsychotics

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	

ARIPIPRAZOLE

Authority required (STREAMLINED)

1589

Schizophrenia

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8717T NP	aripiprazole 10 mg tablet, 30	1	5	..	152.59	37.70	Abilify	BQ
8718W NP	aripiprazole 15 mg tablet, 30	1	5	..	212.90	37.70	Abilify	BQ
8719X NP	aripiprazole 20 mg tablet, 30	1	5	..	253.77	37.70	Abilify	BQ
8720Y NP	aripiprazole 30 mg tablet, 30	1	5	..	303.83	37.70	Abilify	BQ

ARIPIPRAZOLE

Authority required (STREAMLINED)

4246

Schizophrenia

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

10224D NP	aripiprazole 300 mg injection: modified release [1 x 300 mg vial] (&) inert substance diluent [1 vial], 1 pack	1	5	..	324.91	37.70	Abilify Maintena	LU
10219W NP	aripiprazole 400 mg injection: modified release [1 x 400 mg vial] (&) inert substance diluent [1 vial], 1 pack	1	5	..	399.95	37.70	Abilify Maintena	LU

PALIPERIDONE

Authority required (STREAMLINED)

4246

Schizophrenia

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

5107T NP	paliperidone 100 mg injection: modified release, 1 syringe	1	5	..	441.03	37.70	Invega Sustenna	JC
5109X NP	paliperidone 150 mg injection: modified release, 1 syringe	1	5	..	441.03	37.70	Invega Sustenna	JC
5100K NP	paliperidone 25 mg injection: modified release, 1 syringe	1	5	..	149.97	37.70	Invega Sustenna	JC
9140C NP	paliperidone 3 mg tablet: modified release, 28 tablets	1	5	..	79.93	37.70	Invega	JC
5102M NP	paliperidone 50 mg injection: modified release, 1 syringe	1	5	..	285.14	37.70	Invega Sustenna	JC
9141D NP	paliperidone 6 mg tablet: modified release, 28 tablets	1	5	..	154.60	37.70	Invega	JC
5103N NP	paliperidone 75 mg injection: modified release, 1 syringe	1	5	..	363.48	37.70	Invega Sustenna	JC
9142E NP	paliperidone 9 mg tablet: modified release, 28 tablets	1	5	..	226.35	37.70	Invega	JC

RISPERIDONE

Authority required (STREAMLINED)

1589

Schizophrenia

Authority required (STREAMLINED)

2272

Adjunctive therapy to mood stabilisers for up to 6 months, of an episode of acute mania associated with bipolar I disorder

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
Note Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
3169T NP	risperidone 1 mg tablet, 60	1	5	..	19.97	21.12	a APO-Risperidone TX a Ozidal RA a Rispa QA a Risperdal JC a Rispericor 1 CR a Risperidone Actavis 1 UA a Risperidone AN EA a Risperidone-DRLA RZ a Risperidone-GA GN a Risperidone generichealth GQ a Risperidone Sandoz SZ a Rispernia ER a Rixadone AF
8792R NP	risperidone 1 mg tablet: orally disintegrating, 28	2	5	..	*22.12	23.27	Risperdal Quicklet JC
8100H NP	risperidone 1 mg/mL oral liquid, 100 mL	1	5	..	118.37	37.70	Risperdal JC
3170W NP	risperidone 2 mg tablet, 60	1	5	..	37.02	37.70	a APO-Risperidone TX a Ozidal RA a Rispa QA a Risperdal JC a Rispericor 2 CR a Risperidone Actavis 2 UA a Risperidone AN EA a Risperidone-DRLA RZ a Risperidone-GA GN a Risperidone generichealth GQ a Risperidone Sandoz SZ a Rispernia ER a Rixadone AF
8794W NP	risperidone 2 mg tablet: orally disintegrating, 28	2	5	..	*37.60	37.70	Risperdal Quicklet JC
3171X NP	risperidone 3 mg tablet, 60	1	5	..	51.83	37.70	a APO-Risperidone TX a Ozidal RA a Rispa QA a Risperdal JC a Rispericor 3 CR a Risperidone Actavis 3 UA a Risperidone AN EA a Risperidone-DRLA RZ a Risperidone-GA GN a Risperidone generichealth GQ a Risperidone Sandoz SZ a Rispernia ER a Rixadone AF
9075P NP	risperidone 3 mg tablet: orally disintegrating, 28	2	5	..	*51.10	37.70	Risperdal Quicklet JC
3172Y NP	risperidone 4 mg tablet, 60	1	5	..	67.00	37.70	a APO-Risperidone TX a Ozidal RA a Rispa QA a Risperdal JC a Rispericor 4 CR a Risperidone AN EA a Risperidone-DRLA RZ

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							a Risperidone-GA	GN
							a Risperidone generichealth	GQ
							a Risperidone Sandoz	SZ
							a Rispernia	ER
							a Rixadone	AF
9076Q NP	risperidone 4 mg tablet: orally disintegrating, 28	2	5	..	*65.20	37.70	Risperdal Quicklet	JC
RISPERIDONE								
<u>Authority required (STREAMLINED)</u>								
2061								
Behavioural disturbances characterised by psychotic symptoms and aggression in patients with dementia where non-pharmacological methods have been unsuccessful								
<u>Authority required (STREAMLINED)</u>								
3083								
Treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a patient aged less than 18 years with autism.								
Continuing PBS-subsidised treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a patient 18 years of age or older with autism who was commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age.								
Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.								
The diagnosis of autism must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or ICD-10 international classification of mental and behavioural disorders								
<u>Caution</u>								
In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalities) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.								
<u>Note</u>								
Shared Care Model:								
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8789N NP	risperidone 1 mg tablet, 60	1	2	..	19.97	21.12	a APO-Risperidone	TX
							a Ozidal	RA
							a Rispa	QA
							a Risperdal	JC
							a Rispericor 1	CR
							a Risperidone Actavis 1	UA
							a Risperidone AN	EA
							a Risperidone-DRLA	RZ
							a Risperidone-GA	GN
							a Risperidone generichealth	GQ
							a Risperidone Sandoz	SZ
							a Rispernia	ER
							a Rixadone	AF
8790P NP	risperidone 1 mg tablet: orally disintegrating, 28	2	2	..	*22.12	23.27	Risperdal Quicklet	JC
9293D NP	risperidone 1 mg/mL oral liquid, 100 mL	1	2	..	118.37	37.70	Risperdal	JC
8788M NP	risperidone 500 microgram tablet: orally disintegrating, 28	2	2	..	*14.42	15.57	Risperdal Quicklet	JC

RISPERIDONE

Authority required (STREAMLINED)

3083

Treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a patient aged less than 18 years with autism.

Continuing PBS-subsidised treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a patient 18 years of age or older with autism who was commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
The diagnosis of autism must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or ICD-10 international classification of mental and behavioural disorders								
Note								
Shared Care Model:								
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
9079W NP	risperidone 2 mg tablet, 60	1	2	..	37.02	37.70	^a APO-Risperidone	TX
							^a Ozidal	RA
							^a Rispa	QA
							^a Risperdal	JC
							^a Rispericor 2	CR
							^a Risperidone Actavis 2	UA
							^a Risperidone AN	EA
							^a Risperidone-DRLA	RZ
							^a Risperidone-GA	GN
							^a Risperidone generichealth	GQ
							^a Risperidone Sandoz	SZ
							^a Rispernia	ER
							^a Rixadone	AF
9080X NP	risperidone 2 mg tablet: orally disintegrating, 28	2	2	..	*37.60	37.70	Risperdal Quicklet	JC

RISPERIDONE

Authority required (STREAMLINED)

1589

Schizophrenia

Authority required (STREAMLINED)

3841

Maintenance treatment, in combination with lithium or sodium valproate, of treatment refractory bipolar I disorder

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8780D NP	risperidone 25 mg injection: modified release [1 x 25 mg vial] (&) inert substance diluent [1 x 2 mL syringe], 1 pack	2	5	..	*277.44	37.70	Risperdal Consta	JC
8781E NP	risperidone 37.5 mg injection: modified release [1 x 37.5 mg vial] (&) inert substance diluent [1 x 2 mL syringe], 1 pack	2	5	..	*353.78	37.70	Risperdal Consta	JC
8782F NP	risperidone 50 mg injection: modified release [1 x 50 mg vial] (&) inert substance diluent [1 x 2 mL syringe], 1 pack	2	5	..	*429.32	37.70	Risperdal Consta	JC

RISPERIDONE

Authority required (STREAMLINED)

2061

Behavioural disturbances characterised by psychotic symptoms and aggression in patients with dementia where non-pharmacological methods have been unsuccessful

Authority required (STREAMLINED)

3083

Treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a patient aged less than 18 years with autism.

Continuing PBS-subsidised treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a patient 18 years of age or older with autism who was commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or ICD-10

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

international classification of mental and behavioural disorders

Caution

In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalities) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.

Note

For item codes 8787L and 1842Y, pharmaceutical benefits that have the form tablet 0.5 mg are equivalent for the purposes of substitution.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1842Y NP	risperidone 500 microgram tablet, 20	3	2	..	*13.63	14.78	^a APO-Risperidone	TX
							^a Risperdal	JC
8787L NP	risperidone 500 microgram tablet, 60	1	2	..	13.63	14.78	^a Ozidal	RA
							^a Rispa	QA
							^a Rispericor 0.5	CR
							^a Risperidone Actavis 0.5	UA
							^a Risperidone AN	EA
							^a Risperidone-DRLA	RZ
							^a Risperidone-GA	GN
							^a Risperidone GH	GQ
							^a Risperidone Sandoz	SZ
							^a Rispernia	ER
							^a Rixadone	AF

RISPERIDONE

Authority required (STREAMLINED)

1589

Schizophrenia

Note

For item codes 8869T and 1846E, pharmaceutical benefits that have the form tablet 0.5 mg are equivalent for the purposes of substitution.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1846E NP	risperidone 500 microgram tablet, 20	3	5	..	*13.63	14.78	^a APO-Risperidone	TX
							^a Risperdal	JC
8869T NP	risperidone 500 microgram tablet, 60	1	5	..	13.63	14.78	^a Ozidal	RA
							^a Rispa	QA
							^a Rispericor 0.5	CR
							^a Risperidone Actavis 0.5	UA
							^a Risperidone AN	EA
							^a Risperidone-DRLA	RZ
							^a Risperidone-GA	GN
							^a Risperidone GH	GQ
							^a Risperidone Sandoz	SZ
							^a Rispernia	ER
							^a Rixadone	AF

RISPERIDONE

Authority required (STREAMLINED)

1589

Schizophrenia

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8870W NP	risperidone 500 microgram tablet: orally disintegrating, 28	2	5	..	*14.42	15.57	Risperdal Quicklet	JC

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
ANXIOLYTICS								
<i>Benzodiazepine derivatives</i>								
ALPRAZOLAM								
<u>Authority required</u>								
Panic disorder where other treatments have failed or are inappropriate								
2132F NP	alprazolam 1 mg tablet, 50	1	2	..	14.75	15.90	^a Alprax 1	QA
							^a Chem mart Alprazolam	CH
							^a GenRx Alprazolam	GX
							^a Kalma 1	AF
							^a Terry White Chemists Alprazolam	TW
8118G NP	alprazolam 2 mg tablet, 50	1	2	..	17.66	18.81	^a Alprax 2	QA
							^a Chem mart Alprazolam	CH
							^a GenRx Alprazolam	GX
							^a Kalma 2	AF
							^a Terry White Chemists Alprazolam	TW
2130D NP	alprazolam 250 microgram tablet, 50	1	..	..	11.34	12.49	^a Alprax 0.25	QA
							^a Kalma 0.25	AF
2131E NP	alprazolam 500 microgram tablet, 50	1	..	..	12.51	13.66	^a Alprax 0.5	QA
							^a Kalma 0.5	AF
DIAZEPAM								
<u>Authority required</u>								
Chronic spasticity								
Population criteria:								
Patient must be under 18 years of age.								
2669L NP	diazepam 1 mg/mL oral liquid, 100 mL	1	..	..	43.12	37.70	Diazepam Elixir	ON
DIAZEPAM								
<u>Note</u>								
Authorities for increased maximum quantities and/or repeats for the oral forms of diazepam will be granted only for								
(i) the treatment of disabling spasticity; or								
(ii) malignant neoplasia (late stage); or								
(iii) use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal; or								
(iv) use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal.								
Up to six months' treatment (i.e. one month's treatment with five repeats) may be requested.								
2558P NP	diazepam 10 mg/2 mL injection, 5 x 2 mL ampoules	1	..	..	13.68	14.83	Hospira Pty Limited	HH
3161J NP	diazepam 2 mg tablet, 50	1	..	..	7.92	9.07	^a Antenex 2	AF
							^a APO-Diazepam	TX
							^a Ranzepam	RA
							^a Valpam 2	QA
3162K NP	diazepam 5 mg tablet, 50	1	..	..	8.04	9.19	^a Antenex 5	AF
							^a APO-Diazepam	TX
							^a Ranzepam	RA
							^a Valpam 5	QA
				^b 2.52	10.56	9.19	^a Valium	RO
DIAZEPAM								
5073B DP	diazepam 10 mg/2 mL injection, 5 x 2 mL ampoules	1	..	..	13.68	14.83	Hospira Pty Limited	HH

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
5071X DP	diazepam 2 mg tablet, 50	1	..	..	7.92	9.07	^a Antenex 2	AF
							^a APO-Diazepam	TX
							^a Ranzepam	RA
							^a Valpam 2	QA
5072Y DP	diazepam 5 mg tablet, 50	1	..	..	8.04	9.19	^a Antenex 5	AF
							^a APO-Diazepam	TX
							^a Ranzepam	RA
							^a Valpam 5	QA
				^B 2.52	10.56	9.19	^a Valium	RO

OXAZEPAM

Note

Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of oxazepam below.

3132W NP	oxazepam 15 mg tablet, 25	1	..	..	8.00	9.15	^a Alepam 15	AF
				^B 2.68	10.68	9.15	^a Serepax	QA
3133X NP	oxazepam 30 mg tablet, 25	1	..	..	8.00	9.15	^a Alepam 30	AF
							^a APO-Oxazepam	TX
							^a Murelax	FM
				^B 2.68	10.68	9.15	^a Serepax	QA

OXAZEPAM

Authority required

Malignant neoplasia (late stage)

Authority required

For use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal

Authority required

For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal

3134Y NP	oxazepam 15 mg tablet, 25	2	5	..	*9.24	10.39	^a Alepam 15	AF
				^B 5.36	*14.60	10.39	^a Serepax	QA
3135B NP	oxazepam 30 mg tablet, 25	2	5	..	*9.24	10.39	^a Alepam 30	AF
							^a APO-Oxazepam	TX
							^a Murelax	FM
				^B 5.36	*14.60	10.39	^a Serepax	QA

OXAZEPAM

5192G DP	oxazepam 15 mg tablet, 25	1	..	..	8.00	9.15	^a Alepam 15	AF
				^B 2.68	10.68	9.15	^a Serepax	QA
5193H DP	oxazepam 30 mg tablet, 25	1	..	..	8.00	9.15	^a Alepam 30	AF
							^a APO-Oxazepam	TX
							^a Murelax	FM
				^B 2.68	10.68	9.15	^a Serepax	QA

HYPNOTICS AND SEDATIVES

Benzodiazepine derivatives

NITRAZEPAM

Note

Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of nitrazepam below.

2723H NP	nitrazepam 5 mg tablet, 25	1	..	..	8.35	9.50	^a Alodorm	AF
				^B 1.24	9.59	9.50	^a Mogadon	IA

NITRAZEPAM

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	<u>Authority required</u> Myoclonic epilepsy							
	<u>Authority required</u> Malignant neoplasia (late stage)							
	<u>Authority required</u> For use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal							
	<u>Authority required</u> For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal							
	<u>Note</u> Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
2732T NP	nitrazepam 5 mg tablet, 25	2	5	..	*9.94	11.09	^a Alodorm	AF
				^B 2.48	*12.42	11.09	^a Mogadon	IA
	NITRAZEPAM							
5189D DP	nitrazepam 5 mg tablet, 25	1	..	..	8.35	9.50	^a Alodorm	AF
				^B 1.24	9.59	9.50	^a Mogadon	IA
	TEMAZEPAM							
	<u>Authority required</u> Malignant neoplasia (late stage)							
	<u>Authority required</u> For use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal							
	<u>Authority required</u> For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal							
	<u>Note</u> Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
2088X NP	temazepam 10 mg tablet, 25	2	5	..	*8.62	9.77	^a APO-Temazepam	TX
							^a Temaze	AF
							^a Temtabs	FM
				^B 8.00	*16.62	9.77	^a Normison	QA
	TEMAZEPAM							
	<u>Note</u> Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of temazepam below.							
2089Y NP	temazepam 10 mg tablet, 25	1	..	..	7.69	8.84	^a APO-Temazepam	TX
							^a Temaze	AF
							^a Temtabs	FM
				^B 4.00	11.69	8.84	^a Normison	QA
	TEMAZEPAM							
5221T DP	temazepam 10 mg tablet, 25	1	..	..	7.69	8.84	^a APO-Temazepam	TX
							^a Temaze	AF
							^a Temtabs	FM
				^B 4.00	11.69	8.84	^a Normison	QA

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

PSYCHOANALEPTICS

ANTIDEPRESSANTS

Non-selective monoamine reuptake inhibitors

AMITRIPTYLINE

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2417F NP	amitriptyline hydrochloride 10 mg tablet, 50	1	2	..	9.65	10.80	^a	APO-Amitriptyline 10	TX
								Chem mart	CH
								Amitriptyline	
								Endep 10	AF
2418G NP	amitriptyline hydrochloride 25 mg tablet, 50	1	2	..	9.87	11.02	^a	Terry White Chemists	TW
								Amitriptyline	
								APO-Amitriptyline 25	TX
								Chem mart	CH
2429W NP	amitriptyline hydrochloride 50 mg tablet, 50	1	2	..	10.33	11.48	^a	Amitriptyline	
								Endep 25	AF
								Terry White Chemists	TW
								Amitriptyline	
							^a	APO-Amitriptyline 50	TX
								Chem mart	CH
								Amitriptyline	
								Endep 50	AF
							^a	Terry White Chemists	TW
								Amitriptyline	

CLOMIPRAMINE

Restricted benefit

Cataplexy associated with narcolepsy

Restricted benefit

Obsessive-compulsive disorder

Restricted benefit

Phobic disorders in adults

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1561E NP	clomipramine hydrochloride 25 mg tablet, 50	1	2	..	14.49	15.64	^a	Chem mart	CH
								Clomipramine	
								GenRx Clomipramine	GX
								Placil	AF
							^a	Terry White Chemists	TW
								Clomipramine	
				^B 2.74	17.23	15.64	^a	Anafranil 25	NV

DOTHIEPIN

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1357K NP	dothiepin hydrochloride 25 mg capsule, 50	1	2	..	9.72	10.87		Dothep 25	AF
1358L NP	dothiepin hydrochloride 75 mg tablet, 30	1	2	..	9.72	10.87		Dothep 75	AF

DOXEPIN

Note

Continuing Therapy Only:

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
1011F NP	doxepin 10 mg capsule, 50	1	2	..	10.26	11.41	Deptran 10	AF
				^B 2.86	13.12	11.41	Sinequan	PF
1013H NP	doxepin 25 mg capsule, 50	1	2	..	10.39	11.54	Deptran 25	AF
				^B 2.73	13.12	11.54	Sinequan	PF
1012G NP	doxepin 50 mg tablet, 50	1	2	..	11.36	12.51	Deptran 50	AF

IMIPRAMINE

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2420J NP	imipramine hydrochloride 10 mg tablet, 50	1	2	..	8.88	10.03	^a Tolerade 10	PQ
				^B 2.79	11.67	10.03	^a Tofranil 10	LM
2421K NP	imipramine hydrochloride 25 mg tablet, 50	1	2	..	12.77	13.92	^a Tolerade 25	PQ
				^B 2.78	15.55	13.92	^a Tofranil 25	LM

NORTRIPTYLINE

Restricted benefit

Major depression where other antidepressant therapy has failed

Restricted benefit

Major depression where other antidepressant therapy is contraindicated

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2522R NP	nortriptyline 10 mg tablet, 50	1	2	..	13.66	14.81	Allegron	AS
2523T NP	nortriptyline 25 mg tablet, 50	1	2	..	15.44	16.59	Allegron	AS

Selective serotonin reuptake inhibitors

CITALOPRAM

Restricted benefit

Major depressive disorders

8702B NP	citalopram 10 mg tablet, 28	1	5	..	8.39	9.54	^a Celapram	AF
							^a Citalopram Actavis	UA
							^a Citalopram-GA	GN
8220P NP	citalopram 20 mg tablet, 28	1	5	..	9.23	10.38	^a APO-Citalopram	TX
							^a Auro-Citalopram 20	DO
							^a Celapram	AF
							^a Celica	RA
							^a Chem mart Citalopram	CH
							^a Ciazil	UA
							^a Citalopram Actavis	VN
							^a Citalopram AN	EA
							^a Citalopram-GA	GN
							^a Citalopram	GQ
							generichealth	
							^a Citalopram Sandoz	SZ
							^a Pharmacor Citalo 20	CR
							^a Talam	QA
							^a Terry White Chemists	TW
							Citalopram	
				^B 5.70	14.93	10.38	^a Cipramil	LU
8703C	citalopram 40 mg tablet, 28	1	5	..	10.95	12.10	^a APO-Citalopram	TX

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
NP								
							a Auro-Citalopram 40	DO
							a Celapram	AF
							a Citalopram Actavis	VN
							a Citalopram AN	EA
							a Citalopram-GA	GN
							a Citalopram Sandoz	SZ
	ESCITALOPRAM							
	<u>Restricted benefit</u>							
	Major depressive disorders							
8700X NP	escitalopram 10 mg tablet, 28	1	5	..	10.97	12.12	a APO-Escitalopram	TX
							a Chem mart	CH
							Escitalopram	
							a Cilopam-S	ER
							a Escicor 10	RA
							a Escitalopram AN	EA
							a Escitalopram-DRLA	RZ
							a Escitalopram GA	GN
							a Escitalopram	GQ
							generichealth	
							a Esipram	UA
							a Esitalo	SZ
							a Lexam 10	QA
							a LoxaLate	AF
							a Pharmacor	CR
							Escitalopram 10	
							a Terry White Chemists	TW
							Escitalopram	
8701Y	escitalopram 20 mg tablet, 28	1	5	^B 4.28	15.25	12.12	a Lexapro	LU
NP				..	11.00	12.15	a APO-Escitalopram	TX
							a Chem mart	CH
							Escitalopram	
							a Cilopam-S	ER
							a Escicor 20	RA
							a Escitalopram AN	EA
							a Escitalopram-DRLA	RZ
							a Escitalopram GA	GN
							a Escitalopram	GQ
							generichealth	
							a Esipram	UA
							a Esitalo	SZ
							a Lexam 20	QA
							a LoxaLate	AF
							a Pharmacor	CR
							Escitalopram 20	
							a Terry White Chemists	TW
							Escitalopram	
				^B 4.95	15.95	12.15	a Lexapro	LU

ESCITALOPRAM

Restricted benefit

Moderate to severe generalised anxiety disorder (GAD)

Clinical criteria:

The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria,

AND

Patient must not have responded to non-pharmacological therapy,

AND

Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

Restricted benefit

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	Moderate to severe generalised anxiety disorder (GAD)						
	Clinical criteria:						
	The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria,						
	AND						
	Patient must not have responded to non-pharmacological therapy,						
	AND						
	Patient must have been assessed by a psychiatrist.						
	Restricted benefit						
	Moderate to severe social anxiety disorder (social phobia, SAD)						
	Clinical criteria:						
	The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria,						
	AND						
	Patient must not have responded to non-pharmacological therapy,						
	AND						
	Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.						
	Restricted benefit						
	Moderate to severe social anxiety disorder (social phobia, SAD)						
	Clinical criteria:						
	The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria,						
	AND						
	Patient must not have responded to non-pharmacological therapy,						
	AND						
	Patient must have been assessed by a psychiatrist.						
9432K NP	escitalopram 10 mg tablet, 28	1	5	..	10.97	12.12	^a Esipram UA
				^b 4.28	15.25	12.12	^a Lexapro LU
9433L NP	escitalopram 20 mg tablet, 28	1	5	..	11.00	12.15	^a Esipram UA
				^b 4.95	15.95	12.15	^a Lexapro LU

ESCITALOPRAM

Restricted benefit

Major depressive disorders

Restricted benefit

Moderate to severe generalised anxiety disorder (GAD)

Clinical criteria:

The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria,

AND

Patient must not have responded to non-pharmacological therapy,

AND

Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

Restricted benefit

Moderate to severe generalised anxiety disorder (GAD)

Clinical criteria:

The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria,

AND

Patient must not have responded to non-pharmacological therapy,

AND

Patient must have been assessed by a psychiatrist.

Restricted benefit

Moderate to severe social anxiety disorder (social phobia, SAD)

Clinical criteria:

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria,								
AND								
Patient must not have responded to non-pharmacological therapy,								
AND								
Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.								
<u>Restricted benefit</u>								
Moderate to severe social anxiety disorder (social phobia, SAD)								
Clinical criteria:								
The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria,								
AND								
Patient must not have responded to non-pharmacological therapy,								
AND								
Patient must have been assessed by a psychiatrist.								
10181W NP	escitalopram 20 mg/mL oral liquid, 15 mL	‡1	5	..	36.63	37.70	Lexapro	LU
FLUOXETINE								
<u>Restricted benefit</u>								
Major depressive disorders								
<u>Restricted benefit</u>								
Obsessive-compulsive disorder								
1434L NP	fluoxetine 20 mg capsule, 28	1	5	..	12.35	13.50	^a Auscap Aspen	QA
							^a Chem mart Fluoxetine	CH
							^a Fluoxetine 20	CR
							^a Fluoxetine AN	EA
							^a Fluoxetine-GA	GN
							^a Fluoxetine generichealth	GQ
							^a Fluoxetine RBX	RA
							^a Fluoxetine Sandoz	SZ
							^a GenRx Fluoxetine	GX
							^a Lovan	AL
							^a Terry White Chemists Fluoxetine	TW
				^B 1.78	14.13	13.50	^a Zactin	AF
8270G NP	fluoxetine 20 mg tablet: dispersible, 28	1	5	..	12.35	13.50	^a Prozac 20	LY
							^a Lovan 20 Tab	AL
				^B 1.78	14.13	13.50	^a Zactin Tablet	AF
							^a Prozac Tab	LY
FLUVOXAMINE								
<u>Restricted benefit</u>								
Major depressive disorders								
<u>Restricted benefit</u>								
Obsessive-compulsive disorder								
8174F NP	fluvoxamine maleate 100 mg tablet, 30	1	5	..	17.95	19.10	^a APO-Fluvoxamine	TX
							^a Faverin 100	QA
							^a Fluvoxamine GA	GN
							^a Movox 100	AF
							^a Voxam	SZ
				^B 3.10	21.05	19.10	^a Luvox	GO
8512B NP	fluvoxamine maleate 50 mg tablet, 30	1	5	..	14.14	15.29	^a APO-Fluvoxamine	TX
							^a Faverin 50	QA
							^a Fluvoxamine GA	GN
							^a Movox 50	AL
							^a Voxam	SZ

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
				^b 3.11	17.25	15.29	^a Luvox	GO
	PAROXETINE							
	<u>Restricted benefit</u>							
	Major depressive disorders							
	<u>Restricted benefit</u>							
	Obsessive-compulsive disorder							
	<u>Restricted benefit</u>							
	Panic disorder							
	<u>Note</u>							
	Pharmaceutical benefits that have the form paroxetine tablet 20 mg (as hydrochloride) and pharmaceutical benefits that have the form paroxetine tablet 20 mg (as mesilate) are equivalent for the purposes of substitution.							
2242B NP	paroxetine 20 mg tablet, 30	1	5	..	12.44	13.59	^a Chem mart Paroxetine	CH
							^a Extine 20	QA
							^a GenRx Paroxetine	GX
							^a Paroxetine Actavis	UA
							^a Paroxetine AN	EA
							^a Paroxetine-GA	GN
							^a Paroxetine Sandoz	SZ
							^a Paxtine	AF
							^a Roxet 20	DO
							^a Terry White Chemists Paroxetine	TW
				^b 2.52	14.96	13.59	^a Aropax	AS
9197C NP	paroxetine 20 mg tablet, 30	1	5	..	12.44	13.59	^a Paroxetine generichealth	GQ
	SERTRALINE							
	<u>Restricted benefit</u>							
	Major depressive disorders							
2237R NP	sertraline 100 mg tablet, 30	1	5	..	9.55	10.70	^a APO-Sertraline	TX
							^a Auro-Sertraline 100	DO
							^a Chem mart Sertraline	CH
							^a Eleva 100	AF
							^a GenRx Sertraline	GX
							^a Sertra 100	QA
							^a Sertracor 100	CR
							^a Sertraline Actavis	UA
							^a Sertraline AN	EA
							^a Sertraline-DRLA	RZ
							^a Sertraline generichealth	GQ
							^a Sertraline Sandoz	SZ
							^a Setrona	RA
							^a Terry White Chemists Sertraline	TW
							^a Xydep 100	GN
				^b 0.59	10.14	10.70	^a Zolofit	PF
2236Q NP	sertraline 50 mg tablet, 30	1	5	..	9.55	10.70	^a APO-Sertraline	TX
							^a Auro-Sertraline 50	DO
							^a Chem mart Sertraline	CH
							^a Eleva 50	AF
							^a GenRx Sertraline	GX
							^a Sertra 50	QA
							^a Sertracor 50	CR
							^a Sertraline Actavis	UA
							^a Sertraline AN	EA
							^a Sertraline-DRLA	RZ
							^a Sertraline generichealth	GQ
							^a Sertraline Sandoz	SZ
							^a Setrona	RA

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							^a Terry White Chemists Sertraline	TW
				^b 0.59	10.14	10.70	^a Xydep 50	GN
							^a Zoloft	PF
SERTRALINE								
<u>Restricted benefit</u>								
Obsessive-compulsive disorder								
<u>Restricted benefit</u>								
Panic disorder where other treatments have failed or are inappropriate								
8837D NP	sertraline 100 mg tablet, 30	1	5	..	9.55	10.70	^a Auro-Sertraline 100	DO
							^a Eleva 100	AF
							^a Sertraline Actavis	UA
							^a Sertraline AN	EA
							^a Xydep 100	GN
				^b 0.59	10.14	10.70	^a Zoloft	PF
8836C NP	sertraline 50 mg tablet, 30	1	5	..	9.55	10.70	^a Auro-Sertraline 50	DO
							^a Eleva 50	AF
							^a Sertraline Actavis	UA
							^a Sertraline AN	EA
							^a Xydep 50	GN
				^b 0.59	10.14	10.70	^a Zoloft	PF
<i>Monoamine oxidase inhibitors, non-selective</i>								
PHENELZINE								
<u>Restricted benefit</u>								
Depression where all other anti-depressant therapy has failed or is inappropriate								
<u>Caution</u>								
This drug is an irreversible monoamine oxidase inhibitor.								
2856H	phenelzine 15 mg tablet, 100	1	1	..	100.44	37.70	Nardil	LM
TRANLYCYPROMINE								
<u>Caution</u>								
This drug is an irreversible monoamine oxidase inhibitor.								
2444P	tranylcypromine 10 mg tablet, 50	1	2	..	58.66	37.70	Parnate	GH
<i>Monoamine oxidase A inhibitors</i>								
MOCLOBEMIDE								
<u>Restricted benefit</u>								
Major depressive disorders								
<u>Note</u>								
Continuing Therapy Only:								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
1900B NP	moclobemide 150 mg tablet, 60	1	5	..	13.14	14.29	^a Amira 150	AF
							^a Chem mart Moclobemide	CH
							^a Clobemix	GN
							^a GenRx Moclobemide	GX
							^a Moclobemide AN	EA
							^a Moclobemide Sandoz	SZ
							^a Mohexal	HX
							^a Terry White Chemists Moclobemide	TW
				^b 0.37	13.51	14.29	^a Aurorix	HM
8003F NP	moclobemide 300 mg tablet, 60	1	5	..	19.04	20.19	^a Amira 300	AF
							^a Chem mart	CH

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							Moclobemide	
							a Clobemix	GN
							a GenRx Moclobemide	GX
							a Moclobemide AN	EA
							a Moclobemide Sandoz	SZ
							a Terry White Chemists	TW
							Moclobemide	
				^B 0.74	19.78	20.19	a Aurorix 300 mg	HM
Other antidepressants								
DESVENLAFAXINE								
Restricted benefit								
Major depressive disorders								
Note								
Continuing Therapy Only:								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
Note								
Pharmaceutical benefits that have the forms desvenlafaxine tablet (modified release) 50 mg, desvenlafaxine tablet (modified release) 50 mg (as benzoate) and desvenlafaxine tablet (extended release) 50 mg (as succinate) are equivalent for the purposes of substitution.								
Note								
Pharmaceutical benefits that have the forms desvenlafaxine tablet (modified release) 100 mg, desvenlafaxine tablet (modified release) 100 mg (as benzoate) and desvenlafaxine tablet (extended release) 100 mg (as succinate) are equivalent for the purposes of substitution.								
10231L NP	desvenlafaxine 100 mg tablet: modified release, 28 tablets	1	5	..	42.75	37.70	a Desfax	AF
10245F NP	desvenlafaxine 100 mg tablet: modified release, 28 tablets	1	5	..	42.75	37.70	a Desvenlafaxine Actavis	GN
9367B NP	desvenlafaxine 100 mg tablet: modified release, 28 tablets	1	5	..	42.75	37.70	a Desvenlafaxine GH XR	GQ
10234P NP	desvenlafaxine 50 mg tablet: modified release, 28 tablets	1	5	..	36.25	37.40	a Pristiq	PF
10241B NP	desvenlafaxine 50 mg tablet: modified release, 28 tablets	1	5	..	36.25	37.40	a Desvenlafaxine GH XR	GQ
9366Y NP	desvenlafaxine 50 mg tablet: modified release, 28 tablets	1	5	..	36.25	37.40	a Desfax	AF
							a Desvenlafaxine Actavis	GN
							a Pristiq	PF
DULOXETINE								
Restricted benefit								
Major depressive disorders								
Note								
Continuing Therapy Only:								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
9155W NP	duloxetine 30 mg capsule: enteric, 28	1	..	..	18.71	19.86	a Andepra	EL
							a APO-Duloxetine	TX
							a Chem mart Duloxetine	CH
							a Coperin	AF
							a Cymbalta	LY
							a Deotine 30	SZ
							a Drulox	GN
							a Duloxetine AN	EA
							a Duloxetine-DRLA	RZ
							a Duloxetine GH	GQ
							a Duloxetine RBX	RA
							a Pharmacor Duloxetine 30	CR
							a Terry White Chemists	TW
9156X NP	duloxetine 60 mg capsule: enteric, 28	1	5	..	23.81	24.96	Duloxetine	
							a Andepra	EL
							a APO-Duloxetine	TX

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							^a Chem mart Duloxetine	CH
							^a Coperin	AF
							^a Cymbalta	LY
							^a Deotine 60	SZ
							^a Drulox	GN
							^a Duloxetine AN	EA
							^a Duloxetine-DRLA	RZ
							^a Duloxetine GH	GQ
							^a Duloxetine RBX	RA
							^a Pharmacor Duloxetine 60	CR
							^a Terry White Chemists Duloxetine	TW

LITHIUM CARBONATE

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

3059B NP	lithium carbonate 250 mg tablet, 200	1	2	..	17.23	18.38	Lithicarb	AS
8290H NP	lithium carbonate 450 mg tablet: modified release, 100 tablets	2	2	..	*34.64	35.79	Quilonum SR	AS

MIANSERIN

Restricted benefit

Severe depression

Caution

Neutropenia and agranulocytosis are more frequent in the elderly, especially in the early months of therapy.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1627P NP	mianserin hydrochloride 10 mg tablet, 50	1	5	..	15.73	16.88	Lumin 10	AF
1628Q NP	mianserin hydrochloride 20 mg tablet, 50	1	5	..	25.68	26.83	Lumin 20	AF

MIRTAZAPINE

Restricted benefit

Major depressive disorders

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8855C NP	MIRTAZAPINE Tablet 15 mg (orally disintegrating), 30	1	5	..	13.55	14.70	^a Milivin OD 15	DO
							^a Mirtazapine AN ODT	EA
							^a Mirtazapine Sandoz ODT 15	SZ
							^a Remeron SolTab	FR
				^B 1.03	14.58	14.70	^a Avanza SolTab	MK
8856D NP	MIRTAZAPINE Tablet 30 mg (orally disintegrating), 30	1	5	..	15.81	16.96	^a Milivin OD 30	DO
							^a Mirtazapine AN ODT	EA
							^a Mirtazapine Sandoz ODT 30	SZ
							^a Remeron SolTab	FR
				^B 1.01	16.82	16.96	^a Avanza SolTab	MK
8857E NP	MIRTAZAPINE Tablet 45 mg (orally disintegrating), 30	1	5	..	20.40	21.55	^a Milivin OD 45	DO
							^a Mirtazapine AN ODT	EA
							^a Mirtazapine Sandoz ODT 45	SZ

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
9365X NP	mirtazapine 15 mg tablet, 30	1	5	^B 1.02	21.42	21.55	^a Remeron SolTab	FR
				..	10.69	11.84	^a Avanza SolTab	MK
							^a APO-Mirtazapine	TX
8513C NP	mirtazapine 30 mg tablet, 30	1	5	..	12.67	13.82	^a Axit 15	AF
							^a Mirtazapine AN	EA
							^a APO-Mirtazapine	TX
							^a Aurozapine 30	DO
							^a Axit 30	AF
							^a Chem mart Mirtazapine	CH
							^a GenRx Mirtazapine	GX
							^a Mirtazapine AN	EA
							^a Mirtazapine-GA	GN
							^a Mirtazapine GH	GQ
8883M NP	mirtazapine 45 mg tablet, 30	1	5	..	16.60	17.75	^a Mirtazapine Sandoz	SZ
							^a Mirtazon	QA
							^a Terry White Chemists Mirtazapine	TW
							^a Aurozapine 45	DO
							^a Avanza	MK
							^a APO-Mirtazapine	TX
							^a Axit 45	AF
							^a Chem mart Mirtazapine	CH
							^a Mirtazapine AN	EA
							^a Mirtazapine-GA	GN
				^B 2.99	19.59	17.75	^a Mirtazapine GH	GQ
							^a Mirtazapine Sandoz	SZ
							^a Mirtazon	QA
				^B 2.99	19.59	17.75	^a Terry White Chemists Mirtazapine	TW
							^a Avanza	MK

REBOXETINE

Restricted benefit

Major depressive disorders

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8583R NP	reboxetine 4 mg tablet, 60	1	5	..	39.10	37.70	Edronax	PF

VENLAFAXINE

Restricted benefit

Major depressive disorders

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8302Y NP	venlafaxine 150 mg capsule: modified release, 28 capsules	1	5	..	18.81	19.96	^a Altven	FZ
							^a APO-Venlafaxine XR	TX
							^a Blooms the Chemist Venlafaxine XR	IB
							^a Chem mart Venlafaxine XR	CH
							^a Efexor-XR	PF
							^a Elaxine SR 150	ZP
							^a Enlafax-XR	AF
							^a Terry White Chemists Venlafaxine XR	TW
							^a Venlafaxine Actavis XR	UA

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
8868R NP	venlafaxine 37.5 mg capsule: modified release, 28 capsules	1	..	..	12.36	13.51	a Venlafaxine AN SR	EA
							a Venlafaxine generichealth XR	GQ
							a Venlafaxine Sandoz XR	SZ
							a Venlafaxine SR SCP 150	CR
							a Venla RBX	RA
							a Venlexor XR	GN
8301X NP	venlafaxine 75 mg capsule: modified release, 28 capsules	1	5	..	16.65	17.80	a Altven	FZ
							a Efexor-XR	PF
							a Elaxine SR 37.5	ZP
							a Venlafaxine Actavis XR	UA
							a Venlafaxine AN SR	EA
							a Altven	FZ
							a APO-Venlafaxine XR	TX
							a Blooms the Chemist Venlafaxine XR	IB
							a Chem mart Venlafaxine XR	CH
							a Efexor-XR	PF
							a Elaxine SR 75	ZP
							a Enlafax-XR	AF
							a Terry White Chemists Venlafaxine XR	TW
							a Venlafaxine Actavis XR	UA
							a Venlafaxine AN SR	EA
							a Venlafaxine generichealth XR	GQ
							a Venlafaxine Sandoz XR	SZ
							a Venlafaxine SR SCP 75	CR
							a Venla RBX	RA
							a Venlexor XR	GN

PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS

Centrally acting sympathomimetics

ATOMOXETINE

Authority required (STREAMLINED)

4591

Attention deficit hyperactivity disorder

Treatment Phase: Initial treatment

Clinical criteria:

The condition must be or have been diagnosed by a paediatrician or psychiatrist according to the DSM-5 criteria,

AND

Patient must have a contraindication to dexamphetamine or methylphenidate as specified in TGA-approved product information; OR

Patient must have a comorbid mood disorder that has developed or worsened as a result of dexamphetamine or methylphenidate treatment and is of a severity necessitating treatment withdrawal; OR

Patient must be at an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal if given a stimulant treatment with another agent; OR

Patient must have experienced adverse reactions of a severity necessitating permanent treatment withdrawal following treatment with dexamphetamine and treatment with methylphenidate (not simultaneously).

Population criteria:

Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

Authority required (STREAMLINED)

4578

Attention deficit hyperactivity disorder

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug.

Note

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
No increase in the maximum quantity or number of units may be authorised.								
Note								
No increase in the maximum number of repeats may be authorised.								
9092M	atomoxetine 10 mg capsule, 28	2	5	..	*221.52	37.70	Strattera	LY
9290Y	atomoxetine 100 mg capsule, 28	1	5	..	147.45	37.70	Strattera	LY
9093N	atomoxetine 18 mg capsule, 28	2	5	..	*221.52	37.70	Strattera	LY
9094P	atomoxetine 25 mg capsule, 28	2	5	..	*221.52	37.70	Strattera	LY
9095Q	atomoxetine 40 mg capsule, 28	2	5	..	*221.52	37.70	Strattera	LY
9096R	atomoxetine 60 mg capsule, 28	2	5	..	*221.52	37.70	Strattera	LY
9289X	atomoxetine 80 mg capsule, 28	1	5	..	147.45	37.70	Strattera	LY

DEXAMPHETAMINE

Authority required

Use in attention deficit hyperactivity disorder, in accordance with State/Territory law

Authority required

Narcolepsy

Note

Care must be taken to comply with the provisions of State/Territory law when prescribing dexamphetamine.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1165H NP	dexamphetamine sulfate 5 mg tablet, 100	1	5	..	18.53	19.68	Aspen Pharma Pty Ltd	QA

METHYLPHENIDATE

Authority required

Treatment of attention deficit hyperactivity disorder (ADHD) in a patient diagnosed between the ages of 6 and 18 years inclusive, who has demonstrated a response to immediate release methylphenidate hydrochloride with no emergence of serious adverse events, and who requires continuous coverage over 8 hours

Note

Care must be taken to comply with the provisions of State/Territory law when prescribing methylphenidate hydrochloride.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

3440C NP	methylphenidate hydrochloride 10 mg capsule: modified release, 30 capsules	1	5	..	34.39	35.54	Ritalin LA	NV
2276T NP	methylphenidate hydrochloride 20 mg capsule: modified release, 30 capsules	1	5	..	44.91	37.70	Ritalin LA	NV
2280B NP	methylphenidate hydrochloride 30 mg capsule: modified release, 30 capsules	1	5	..	52.37	37.70	Ritalin LA	NV
2283E NP	methylphenidate hydrochloride 40 mg capsule: modified release, 30 capsules	1	5	..	54.90	37.70	Ritalin LA	NV

METHYLPHENIDATE

Authority required

Use in attention deficit hyperactivity disorder, in accordance with State/Territory law

Note

Care must be taken to comply with the provisions of State/Territory law when prescribing methylphenidate hydrochloride.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
8839F NP	methylphenidate hydrochloride 10 mg tablet, 100	1	5	..	17.23	18.38	Ritalin 10	NV

METHYLPHENIDATE

Authority required

Treatment of attention deficit hyperactivity disorder (ADHD) in a patient diagnosed between the ages of 6 and 18 years inclusive, who has demonstrated a response to immediate release methylphenidate hydrochloride with no emergence of serious adverse events, and who requires continuous coverage over 12 hours

Note

Care must be taken to comply with the provisions of State/Territory law when prescribing methylphenidate hydrochloride.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2387P NP	methylphenidate hydrochloride 18 mg tablet: modified release, 30 tablets	1	5	..	51.66	37.70	Concerta	JC
2172H NP	methylphenidate hydrochloride 27 mg tablet: modified release, 30 tablets	1	5	..	55.80	37.70	Concerta	JC
2388Q NP	methylphenidate hydrochloride 36 mg tablet: modified release, 30 tablets	1	5	..	60.03	37.70	Concerta	JC
2432B NP	methylphenidate hydrochloride 54 mg tablet: modified release, 30 tablets	1	5	..	70.09	37.70	Concerta	JC

MODAFINIL

Authority required

Initial treatment, by a qualified sleep medicine practitioner or neurologist, of patients with narcolepsy where:

- (i) therapy with dexamphetamine sulfate poses an unacceptable medical risk; or
- (ii) intolerance to dexamphetamine sulfate of a severity necessitating treatment withdrawal develops.

The presence of any 1 of the following indicates treatment with dexamphetamine sulfate poses an unacceptable medical risk:

- (a) a psychiatric disorder;
- (b) a cardiovascular disorder;
- (c) a history of substance abuse;
- (d) glaucoma;
- (e) any other absolute contraindication to dexamphetamine sulfate as specified in the TGA-approved Product Information.

Patients must meet the following definition of narcolepsy:

Excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months and:

- (i) a definite history of cataplexy;

or

a mean sleep latency less than or equal to 10 minutes on a Multiple Sleep Latency Test (MSLT). The MSLT must be preceded by nocturnal polysomnography. Sleep prior to the MSLT must be at least 6 hours in duration;

or

an electroencephalographic (EEG) recording showing the pathologically rapid development of REM sleep; and

- (ii) absence of any medical or psychiatric disorder that could otherwise account for the hypersomnia.

The authority application must be made in writing and must include the following:

- (a) a completed authority prescription form; and
- (b) a completed Modafinil (Modavigil) PBS Authority Application for Use in the Treatment of Narcolepsy - Supporting Information Form [www.medicareaustralia.gov.au]; and
- (c) details of the contraindication or intolerance to dexamphetamine sulfate; and
- (d) either:
 - (i) the result and date of the polysomnography test and MSLT conducted by, or under the supervision of, a qualified sleep medicine practitioner; or
 - (ii) the result and date of the EEG, conducted by, or under the supervision of, a neurologist.

The polysomnography, MSLT or EEG test reports must be provided with the authority application

Authority required

Continuing treatment of narcolepsy, where the patient has previously been issued with an authority prescription for this drug

Note

Any queries concerning the arrangements to prescribe modafinil may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Written applications for authority to prescribe modafinil should be forwarded to:							
	Medicare Australia							
	Prior Written Approval of Specialised Drugs							
	Reply Paid 9826							
	GPO Box 9826							
	HOBART TAS 7001							
	Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au .							
	Note							
	Modafinil is not PBS-subsidised when used in combination with PBS-subsidised dexamphetamine sulfate.							
8816B	modafinil 100 mg tablet, 60	2	5	..	*347.32	37.70	Modavigil	CS

ANTI-DEMENTIA DRUGS

Anticholinesterases

DONEPEZIL

Authority required (STREAMLINED)

4219

Mild to moderately severe Alzheimer disease

Treatment Phase: Continuing

Clinical criteria:

Patient must have received six months of sole PBS-subsidised initial therapy with this drug,

AND

Patient must demonstrate a clinically meaningful response to the initial treatment,

AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

Patient's quality of life including but not limited to level of independence and happiness;

Patient's cognitive function including but not limited to memory, recognition and interest in environment;

Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2479L NP	donepezil hydrochloride 10 mg tablet, 28	1	5	..	39.64	37.70	^a APO-Donepezil	TX
							^a Arazil	AF
							^a Aricept	PF
							^a Aridon 10	QA
							^a Aridon APN 10	FM
							^a Chem mart Donepezil	CH
							^a Donepezil AN	EA
							^a Donepezil-DRLA	RZ
							^a Donepezil-GA	GN
							^a Donepezil	GQ
							generichealth	
							^a Donepezil RBX	RA
							^a Donepezil Sandoz	SZ
							^a Pharmacor Donepezil 10	CR
							^a Terry White Chemists Donepezil	TW
2532G NP	donepezil hydrochloride 5 mg tablet, 28	1	5	..	39.64	37.70	^a APO-Donepezil	TX
							^a Arazil	AF

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							a Aricept	PF
							a Aridon 5	QA
							a Aridon APN 5	FM
							a Chem mart Donepezil	CH
							a Donepezil AN	EA
							a Donepezil-DRLA	RZ
							a Donepezil-GA	GN
							a Donepezil	GQ
							generichealth	
							a Donepezil RBX	RA
							a Donepezil Sandoz	SZ
							a Pharmacor Donepezil 5	CR
							a Terry White Chemists Donepezil	TW

DONEPEZIL

Authority required

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

Clinical criteria:

Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more,

AND

The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist),

AND

The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

Authority required

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

Clinical criteria:

Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less,

AND

The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist),

AND

The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below.

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

- (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
- (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
- (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;
- (4) Intellectual (developmental or acquired) disability, eg Down's syndrome;
- (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;
- (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.							
Note Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
8496E NP	donepezil hydrochloride 10 mg tablet, 28	1	5	..	39.64	37.70	a APO-Donepezil TX a Arazil AF a Aricept PF a Aridon 10 QA a Aridon APN 10 FM a Chem mart Donepezil CH a Donepezil AN EA a Donepezil-DRLA RZ a Donepezil-GA GN a Donepezil GQ generichealth a Donepezil RBX RA a Donepezil Sandoz SZ a Pharmacor Donepezil 10 CR a Terry White Chemists Donepezil TW
8495D NP	donepezil hydrochloride 5 mg tablet, 28	1	5	..	39.64	37.70	a APO-Donepezil TX a Arazil AF a Aricept PF a Aridon 5 QA a Aridon APN 5 FM a Chem mart Donepezil CH a Donepezil AN EA a Donepezil-DRLA RZ a Donepezil-GA GN a Donepezil GQ generichealth a Donepezil RBX RA a Donepezil Sandoz SZ a Pharmacor Donepezil 5 CR a Terry White Chemists Donepezil TW

GALANTAMINE

Authority required (STREAMLINED)

4219

Mild to moderately severe Alzheimer disease

Treatment Phase: Continuing

Clinical criteria:

Patient must have received six months of sole PBS-subsidised initial therapy with this drug,

AND

Patient must demonstrate a clinically meaningful response to the initial treatment,

AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

Patient's quality of life including but not limited to level of independence and happiness;

Patient's cognitive function including but not limited to memory, recognition and interest in environment;

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.							
Note							
Continuing Therapy Only:							
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.							
2537M NP	galantamine 16 mg capsule: modified release, 28 capsules	1	5	..	51.20	37.70	^a APO-Galantamine MR TX
							^a Galantamine AN SR EA
							^a Galantyl AF
							^a Gamine XR QA
							^a Reminyl JC
2531F NP	galantamine 24 mg capsule: modified release, 28 capsules	1	5	..	59.12	37.70	^a APO-Galantamine MR TX
							^a Galantamine AN SR EA
							^a Galantyl AF
							^a Gamine XR QA
							^a Reminyl JC
2463P NP	galantamine 8 mg capsule: modified release, 28 capsules	1	5	..	43.91	37.70	^a APO-Galantamine MR TX
							^a Galantamine AN SR EA
							^a Galantyl AF
							^a Gamine XR QA
							^a Reminyl JC

GALANTAMINE

Authority required

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

Clinical criteria:

Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more,

AND

The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist),

AND

The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

Authority required

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

Clinical criteria:

Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less,

AND

The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist),

AND

The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below.

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

- (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
- (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;						
	(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;						
	(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;						
	(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.						
	The application must be made in writing, but initial supply may be sought by telephone.						
	For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.						
	For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.						
	<u>Note</u>						
	Continuing Therapy Only:						
	For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.						
8771P NP	galantamine 16 mg capsule: modified release, 28 capsules	1	5	..	51.20	37.70	a APO-Galantamine MR TX a Galantamine AN SR EA a Galantyl AF a Gamine XR QA a Reminyl JC
8772Q NP	galantamine 24 mg capsule: modified release, 28 capsules	1	5	..	59.12	37.70	a APO-Galantamine MR TX a Galantamine AN SR EA a Galantyl AF a Gamine XR QA a Reminyl JC
8770N NP	galantamine 8 mg capsule: modified release, 28 capsules	1	5	..	43.91	37.70	a APO-Galantamine MR TX a Galantamine AN SR EA a Galantyl AF a Gamine XR QA a Reminyl JC

RIVASTIGMINE

Authority required (STREAMLINED)

4219

Mild to moderately severe Alzheimer disease

Treatment Phase: Continuing

Clinical criteria:

Patient must have received six months of sole PBS-subsidised initial therapy with this drug,

AND

Patient must demonstrate a clinically meaningful response to the initial treatment,

AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

Patient's quality of life including but not limited to level of independence and happiness;

Patient's cognitive function including but not limited to memory, recognition and interest in environment;

Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2475G NP	rivastigmine 1.5 mg capsule, 56	1	5	..	96.18	37.70	Exelon NV

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
2476H NP	rivastigmine 2 mg/mL oral liquid, 120 mL	1	5	..	96.18	37.70	Exelon	NV
2493F NP	rivastigmine 3 mg capsule, 56	1	5	..	96.18	37.70	Exelon	NV
2494G NP	rivastigmine 4.5 mg capsule, 56	1	5	..	96.18	37.70	Exelon	NV
2477J NP	rivastigmine 4.6 mg/24 hours patch, 30	1	5	..	102.56	37.70	Exelon Patch 5	NV
2526Y NP	rivastigmine 6 mg capsule, 56	1	5	..	96.18	37.70	Exelon	NV
2551G NP	rivastigmine 9.5 mg/24 hours patch, 30	1	5	..	102.56	37.70	Exelon Patch 10	NV

RIVASTIGMINE

Authority required

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

Clinical criteria:

Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more,

AND

The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist),

AND

The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

Authority required

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

Clinical criteria:

Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less,

AND

The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist),

AND

The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below.

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

- (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
- (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
- (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;
- (4) Intellectual (developmental or acquired) disability, eg Down's syndrome;
- (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;
- (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

Note

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
Continuing Therapy Only:								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
8497F NP	rivastigmine 1.5 mg capsule, 56	1	5	..	96.18	37.70	Exelon	NV
8563Q NP	rivastigmine 2 mg/mL oral liquid, 120 mL	±1	5	..	96.18	37.70	Exelon	NV
8498G NP	rivastigmine 3 mg capsule, 56	1	5	..	96.18	37.70	Exelon	NV
8499H NP	rivastigmine 4.5 mg capsule, 56	1	5	..	96.18	37.70	Exelon	NV
9161E NP	rivastigmine 4.6 mg/24 hours patch, 30	1	5	..	102.56	37.70	Exelon Patch 5	NV
8500J NP	rivastigmine 6 mg capsule, 56	1	5	..	96.18	37.70	Exelon	NV
9162F NP	rivastigmine 9.5 mg/24 hours patch, 30	1	5	..	102.56	37.70	Exelon Patch 10	NV

Other anti-dementia drugs

MEMANTINE

Authority required

Moderately severe Alzheimer disease

Treatment Phase: Initial

Clinical criteria:

Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 to 14,

AND

The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist),

AND

The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE of 10 to 14.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

Authority required

Moderately severe Alzheimer disease

Treatment Phase: Initial

Clinical criteria:

Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less,

AND

The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist),

AND

The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 to 14 for reasons other than their Alzheimer disease, as specified below.

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

- (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
- (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
- (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;
- (4) Intellectual (developmental or acquired) disability, eg Down's syndrome;
- (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;
- (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.								
For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.								
Note								
Continuing Therapy Only:								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
1956Y NP	memantine hydrochloride 10 mg tablet, 56	1	5	..	67.08	37.70	a APO-Memantine	TX
							a Ebixa	LU
							a Memantine generichealth	GQ
							a Memantine RBX	RA
							a Memanxa	QA
9306T NP	memantine hydrochloride 20 mg tablet, 28	1	5	..	67.08	37.70	a APO-Memantine	TX
							a Ebixa	LU
							a Memantine generichealth	GQ
							a Memantine RBX	RA

MEMANTINE

Authority required (STREAMLINED)

4214

Moderately severe Alzheimer disease

Treatment Phase: Continuing

Clinical criteria:

Patient must have received six months of sole PBS-subsidised initial therapy with this drug,

AND

Patient must demonstrate a clinically meaningful response to the initial treatment,

AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

Patient's quality of life including but not limited to level of independence and happiness;

Patient's cognitive function including but not limited to memory, recognition and interest in environment;

Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2492E NP	memantine hydrochloride 10 mg tablet, 56	1	5	..	67.08	37.70	a APO-Memantine	TX
							a Ebixa	LU
							a Memantine generichealth	GQ
							a Memantine RBX	RA
							a Memanxa	QA
2513G NP	memantine hydrochloride 20 mg tablet, 28	1	5	..	67.08	37.70	a APO-Memantine	TX
							a Ebixa	LU
							a Memantine generichealth	GQ
							a Memantine RBX	RA

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	

OTHER NERVOUS SYSTEM DRUGS

PARASYMPATHOMIMETICS

Anticholinesterases

PYRIDOSTIGMINE

2724J	PYRIDOSTIGMINE BROMIDE Tablet 10 mg, 50	2	5	..	*23.34	24.49	Mestinon	IA
2608G	pyridostigmine bromide 180 mg tablet: modified release, 50 tablets	2	5	..	*149.56	37.70	Mestinon Timespan	IA
1959D	pyridostigmine bromide 60 mg tablet, 150	1	5	..	71.66	37.70	Mestinon	IA

Choline esters

BETHANECHOL

1062X NP	bethanechol chloride 10 mg tablet, 100	1	2	..	33.87	35.02	Uro-Carb	YN

DRUGS USED IN ADDICTIVE DISORDERS

Drugs used in nicotine dependence

BUPROPION

Authority required

Commencement of short-term, sole PBS-subsidised, therapy as an aid to achieving abstinence in a patient who has indicated they are ready to cease smoking and who has entered a comprehensive support and counselling program. Details of the program must be specified in the authority application

Authority required

Commencement of short-term, sole PBS-subsidised, therapy as an aid to achieving abstinence in a patient who has indicated they are ready to cease smoking and who is entering a comprehensive support and counselling program during the consultation at which this authority is requested. Details of the program must be specified in the authority application

Note

Only one course of PBS-subsidised bupropion hydrochloride will be authorised per 12 months. The period between commencing a course of bupropion hydrochloride and varenicline tartrate must be at least 6 months. A course of treatment with bupropion hydrochloride is 9 weeks. No increased maximum quantities or repeats will be authorised. Clinical review is recommended within 2 to 3 weeks of the original prescription being requested.

8465M NP	bupropion hydrochloride 150 mg tablet: modified release, 30 tablets	1	..	..	63.34	37.70	^a Prexaton	GN
				^b 0.80	64.14	37.70	^a Zyban	AS

BUPROPION

Authority required

Completion of short-term, sole PBS-subsidised, therapy as an aid to achieving abstinence in a patient who has previously been issued with an authority prescription for this drug and who is enrolled in a comprehensive support and counselling program

Note

Only one course of PBS-subsidised bupropion hydrochloride will be authorised per 12 months. The period between commencing a course of bupropion hydrochloride and varenicline tartrate must be at least 6 months. A course of treatment with bupropion hydrochloride is 9 weeks. No increased maximum quantities or repeats will be authorised. Clinical review is recommended within 2 to 3 weeks of the original prescription being requested.

8710K NP	bupropion hydrochloride 150 mg tablet: modified release, 90 tablets	1	..	..	176.50	37.70	^a Prexaton	GN
				^b 0.96	177.46	37.70	^a Zyban	AS

NICOTINE

Authority required (STREAMLINED)

4348

Nicotine dependence

Clinical criteria:

The treatment must be the sole PBS-subsidised therapy for this condition,

AND

Patient must have indicated they are ready to cease smoking,

AND

Patient must have entered a comprehensive support and counselling program,

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
AND								
Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.								
Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.								
<u>Authority required (STREAMLINED)</u>								
4307								
Nicotine dependence								
Clinical criteria:								
The treatment must be the sole PBS-subsidised therapy for this condition,								
AND								
Patient must have indicated they are ready to cease smoking,								
AND								
Patient must be entering a comprehensive support and counselling program during the consultation at which this prescription is written,								
AND								
Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.								
Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.								
<u>Note</u>								
No increase in the maximum quantity or number of units may be authorised.								
<u>Note</u>								
No increase in the maximum number of repeats may be authorised.								
5572G	nicotine 14 mg/24 hours patch, 28	1	2	..	55.56	37.70	Nicotinell Step 2	NC
NP								
3414Q	nicotine 21 mg/24 hours patch, 28	1	2	..	55.56	37.70	Nicotinell Step 1	NC
NP								
5573H	nicotine 7 mg/24 hours patch, 28	1	2	..	55.56	37.70	Nicotinell Step 3	NC
NP								

NICOTINE

Authority required (STREAMLINED)

4344

Nicotine dependence

Clinical criteria:

The treatment must be the sole PBS-subsidised therapy for this condition.

Population criteria:

Patient must be an Aboriginal or a Torres Strait Islander person.

Note

Only 2 courses of PBS-subsidised nicotine replacement therapy may be prescribed per 12-month period.

Benefit is improved if used in conjunction with a comprehensive support and counselling program.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

4348

Nicotine dependence

Clinical criteria:

The treatment must be the sole PBS-subsidised therapy for this condition,

AND

Patient must have indicated they are ready to cease smoking,

AND

Patient must have entered a comprehensive support and counselling program,

AND

Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

Note

No increase in the maximum quantity or number of units may be authorised.

Treatment criteria:

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.							
	Note							
	A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.							
	Note							
	A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.							
	Note							
	No increase in the maximum quantity or number of units may be authorised.							
	Note							
	No increase in the maximum number of repeats may be authorised.							
5469W NP	varenicline 1 mg tablet, 56	1	2	..	120.76	37.70	Champix	PF

VARENICLINE

Authority required

Nicotine dependence

Treatment Phase: Continuation of a short-term (12 weeks or 24 weeks) course of treatment

Clinical criteria:

The treatment must be as an aid to achieving abstinence from smoking,

AND

The treatment must be the sole PBS-subsidised therapy for this condition,

AND

Patient must have previously been issued with an authority prescription for this drug during this current course of treatment.

Treatment criteria:

Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.

Note

A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.

Note

A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

9129L NP	varenicline 1 mg tablet, 56	2	..	..	*232.04	37.70	Champix	PF

VARENICLINE

Authority required

Nicotine dependence

Treatment Phase: Commencement of a short-term (12 weeks or 24 weeks) course of treatment

Clinical criteria:

The treatment must be as an aid to achieving abstinence from smoking,

AND

The treatment must be the sole PBS-subsidised therapy for this condition,

AND

Patient must have indicated they are ready to cease smoking.

Treatment criteria:

Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time the Authority application is requested.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

Clinical review is recommended within 2 to 3 weeks of the initial prescription being requested.

Note

A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.

Note

The period between commencing varenicline and bupropion or a new course of varenicline must be at least 6 months.

Note

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.								
Note								
No increase in the maximum quantity or number of units may be authorised.								
Note								
No increase in the maximum number of repeats may be authorised.								
9128K NP	varenicline 500 microgram tablet [11 tablets] (&) varenicline 1 mg tablet [42 tablets], 53	\$1	..	..	103.46	37.70	Champix	PF
Drugs used in alcohol dependence								
ACAMPROSATE								
Authority required (STREAMLINED)								
2665								
For use within a comprehensive treatment program for alcohol dependence with the goal of maintaining abstinence								
Note								
No applications for increased maximum quantities and/or repeats will be authorised.								
8357W NP	acamprosate calcium 333 mg tablet: enteric, 180 tablets	1	1	..	166.92	37.70	Campral	AF
NALTREXONE								
Authority required								
For use within a comprehensive treatment program for alcohol dependence with the goal of maintaining abstinence								
Caution								
Naltrexone hydrochloride is contraindicated in patients receiving opioid drugs.								
Note								
No applications for increased maximum quantities and/or repeats will be authorised.								
8370M NP	naltrexone hydrochloride 50 mg tablet, 30	1	1	..	136.01	37.70	^a Naltrexone GH	GQ
							^a ReVia	BQ

OTHER NERVOUS SYSTEM DRUGS

Other nervous system drugs

DIMETHYL FUMARATE

Authority required

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient,

AND

The treatment must be as monotherapy,

AND

Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years,

AND

Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

Special Pricing Arrangements apply.

2896K	dimethyl fumarate 120 mg capsule, 14	1	..	..	491.31	37.70	Tecfidera	BD

DIMETHYL FUMARATE

Authority required

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord: OR

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient.

AND

The treatment must be as monotherapy.

AND

Patient must have previously been issued with an authority prescription for this drug; OR

Patient must have been receiving treatment with this drug prior to 1 December 2013.

AND

Patient must not show continuing progression of disability while on treatment with this drug.

Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application.

Note

Special Pricing Arrangements apply.

2943X	dimethyl fumarate 120 mg capsule, 14	1	..	..	491.31	37.70	Tecfidera	BD

Authority required

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient.

AND

The treatment must be as monotherapy.

AND

Patient must have previously been issued with an authority prescription for this drug; OR

Patient must have been receiving treatment with this drug prior to 1 December 2013.

AND

Patient must not show continuing progression of disability while on treatment with this drug.

Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

Special Pricing Arrangements apply.

2966D	dimethyl fumarate 240 mg capsule, 56	1	5	..	1880.00	37.70	Tecfidera	BD

Authority required

Initial treatment of amyotrophic lateral sclerosis, as diagnosed by a neurologist, in patients with disease duration of 5 years or less and who have at least 60 percent of predicted forced vital capacity within 2 months prior to commencing riluzole therapy and who:

- (1) are ambulatory, and
(a) have not undergone tracheostomy, and
(b) have not experienced respiratory failure; OR
(2) are not ambulatory, and

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	(a) have not undergone tracheostomy, and (b) have not experienced respiratory failure, and (c) are either able to use upper limbs or able to swallow. The date of diagnosis and the date and results of spirometry (in terms of percent of predicted forced vital capacity) must be supplied with the initial authority application Authority required Continuing treatment of amyotrophic lateral sclerosis in patients who have previously been issued with an authority prescription for this drug and who: (1) are ambulatory, and (a) have not undergone tracheostomy, and (b) have not experienced respiratory failure; OR (2) are not ambulatory, and (a) have not undergone tracheostomy, and (b) have not experienced respiratory failure, and (c) are either able to use upper limbs or able to swallow Note Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.						
8664B NP	riluzole 50 mg tablet, 56	1	5	..	369.92	37.70	a APO-Riluzole TX a Pharmacor Riluzole CR a Rilutek SW a Riluzole Sandoz SZ

TETRABENAZINE

Authority required (STREAMLINED)

1161

Hyperkinetic extrapyramidal disorders

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1330B NP	tetrabenazine 25 mg tablet, 112	1	5	..	364.25	37.70	iNova Pharmaceuticals (Australia) Pty Ltd	IA

ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS

ANTIPROTOZOALS

AGENTS AGAINST AMOEBIASIS AND OTHER PROTOZOAL DISEASES

Other agents against amoebiasis and other protozoal diseases

ATOVAQUONE

Authority required (STREAMLINED)

1433

Treatment of mild to moderate *Pneumocystis carinii* pneumonia in adult patients who are intolerant of trimethoprim/sulfamethoxazole therapy

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8300W NP	atovaquone 750 mg/5 mL oral liquid, 210 mL	\$1	..	..	1034.91	37.70	Wellvone	AS

PYRIMETHAMINE

1966L NP	pyrimethamine 25 mg tablet, 50	1	..	..	16.72	17.87	Daraprim	AS

ANTIMALARIALS

Biguanides

ATOVAQUONE + PROGUANIL

Authority required

Treatment of suspected or confirmed *Plasmodium falciparum* malaria in a patient aged 3 years or older where quinine containing regimens are inappropriate

Note

Atovaquone with proguanil hydrochloride is not PBS-subsidised for the prophylaxis of malaria.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

9439T NP	atovaquone 250 mg + proguanil hydrochloride 100 mg tablet, 12	1	..	..	67.34	37.70	Malarone	GK

Methanolquinolines

QUININE

Authority required (STREAMLINED)

2142

Malaria

Caution

Severe thrombocytopenia has been reported with this drug.

1975Y NP	quinine sulfate 300 mg tablet, 50	1	2	..	14.48	15.63	Quinate	AS

Artemisinin and derivatives, combinations

ARTEMETHER + LUMEFANTRINE

Authority required

Treatment of suspected or confirmed malaria due to *Plasmodium falciparum*

Note

Artemether with lumefantrine is not PBS-subsidised for prophylaxis of malaria.

9498X	artemether 20 mg + lumefantrine 120 mg tablet, 24	1	..	..	97.24	37.70	Riamet	NV

ARTEMETHER + LUMEFANTRINE

Authority required

Treatment of suspected or confirmed malaria due to *Plasmodium falciparum* in a patient unable to swallow a solid dosage form of artemether with

ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	lumefantrine							
	Note Artemether with lumefantrine is not PBS-subsidised for prophylaxis of malaria.							
5296R	artemether 20 mg + lumefantrine 120 mg tablet: dispersible, 18	1	..	..	97.24	37.70	Riamet 20mg/120mg Dispersible	NV

ANTHELMINTICS

ANTITREMATODALS

Quinoline derivatives and related substances

PRAZIQUANTEL

Authority required (STREAMLINED)

3147

Schistosomiasis

9447F NP	praziquantel 600 mg tablet, 8	1	..	..	41.19	37.70	Biltricide	BN

ANTINEMATODAL AGENTS

Benzimidazole derivatives

ALBENDAZOLE

Authority required (STREAMLINED)

1525

Treatment of tapeworm infestation

8503M NP	albendazole 200 mg tablet: chewable, 6	1	1	..	33.44	34.59	Zentel	AS

ALBENDAZOLE

Authority required (STREAMLINED)

2446

Treatment of whipworm infestation in an Aboriginal or a Torres Strait Islander person

Authority required (STREAMLINED)

1388

Strongyloidiasis

Authority required (STREAMLINED)

3241

Treatment of hookworm infestation

9047E NP	albendazole 200 mg tablet: chewable, 6	1	..	..	33.44	34.59	Zentel	AS

ALBENDAZOLE

Authority required (STREAMLINED)

1496

For the treatment of hydatid disease in conjunction with surgery or when a surgical cure cannot be achieved or where surgery cannot be used

8459F	albendazole 400 mg tablet: chewable, 60	1	2	..	185.59	37.70	Eskazole	AS

Tetrahydropyrimidine derivatives

PYRANTEL

3047J NP	pyrantel 125 mg tablet, 6	1	..	..	14.94	16.09	Anthel 125	AF

3048K NP	pyrantel 250 mg tablet, 6	1	..	..	23.11	24.26	Anthel 250	AF

Avermectines

IVERMECTIN

Authority required (STREAMLINED)

4328

Strongyloidiasis

Authority required (STREAMLINED)

4565

Crusted (Norwegian) scabies

Clinical criteria:

ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	The condition must be established by clinical and/or parasitological examination, AND Patient must be undergoing topical therapy for this condition; OR Patient must have a contraindication to topical treatment. Population criteria: Patient must weigh 15 kg or over, AND Patient must be 5 years of age or older. <u>Authority required (STREAMLINED)</u> 4566 Human sarcoptic scabies Clinical criteria: The condition must be established by clinical and/or parasitological examination, AND Patient must have completed and failed sequential treatment with topical permethrin and benzyl benzoate and finished the most recent course of topical therapy at least 4 weeks prior to initiating oral therapy; OR Patient must have a contraindication to topical treatment. Population criteria: Patient must weigh 15 kg or over, AND Patient must be 5 years of age or older. <u>Note</u> This drug is not PBS-subsidised for first line treatment of typical scabies.						
2868Y NP	ivermectin 3 mg tablet, 4	2	2	..	*54.54	37.70	Stromectol MK
	IVERMECTIN <u>Authority required (STREAMLINED)</u> 4319 Onchocerciasis						
8359Y NP	ivermectin 3 mg tablet, 4	1	..	..	31.65	32.80	Stromectol MK

ECTOPARASITICIDES, INCL. SCABICIDES, INSECTICIDES AND REPELLENTS

ECTOPARASITICIDES, INCL. SCABICIDES

Pyrethrines, incl. synthetic compounds

3054R NP	PERMETHRIN permethrin 5% cream, 30 g	†1	1	..	17.11	18.26	Lyclear JT

RESPIRATORY SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

RESPIRATORY SYSTEM

NASAL PREPARATIONS

DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE

Other nasal preparations

MUPIROCIN

Authority required (STREAMLINED)

3136

Nasal colonisation with Staphylococcus aureus in an Aboriginal or a Torres Strait Islander person

Note

No applications for increased maximum quantities and/or repeats will be authorised.

9440W NP	mupirocin 2% (20 mg/g) ointment, 3 g	\$1	..	..	20.97	22.12	Bactroban	GK

DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

ADRENERGICS, INHALANTS

Selective beta-2-adrenoreceptor agonists

EFORMOTEROL

Restricted benefit

Patients with frequent episodes of asthma who are currently receiving treatment with oral corticosteroids

Restricted benefit

Patients with frequent episodes of asthma who are currently receiving treatment with optimal doses of inhaled corticosteroids

8136F NP	eformoterol fumarate dihydrate 12 microgram inhalation: powder for, 60 capsules	1	5	..	37.67	37.70	Foradile	NV
8240Q NP	eformoterol fumarate dihydrate 12 microgram/actuation inhalation: powder for, 60 actuations	\$1	5	..	36.78	37.70	Oxis Turbuhaler	AP
8239P NP	eformoterol fumarate dihydrate 6 microgram/actuation inhalation: powder for, 60 actuations	\$1	5	..	26.72	27.87	Oxis Turbuhaler	AP

INDACATEROL

Restricted benefit

Chronic obstructive pulmonary disease

Note

Indacaterol is not PBS-subsidised for the treatment of asthma.

5134F NP	indacaterol 150 microgram inhalation: powder for, 30 capsules	1	5	..	62.73	37.70	Onbrez	NV
5137J NP	indacaterol 300 microgram inhalation: powder for, 30 capsules	1	5	..	62.73	37.70	Onbrez	NV

SALBUTAMOL

8288F NP	salbutamol 100 microgram/actuation inhalation: pressurised, 200	2	5	..	*14.14	15.29	^a APO-Salbutamol Inhaler	TX
				^b 2.34	*16.48	15.29	^a Asmol CFC-free	AL
10143W NP	salbutamol 200 microgram inhalation: powder for, 128 capsules	2	4	..	*19.12	20.27	^a Ventolin CFC-free Ventolin Rotacaps	GK GK

SALBUTAMOL

Restricted benefit

Asthma in patients unable to use this drug delivered from an oral pressurised inhalation device via a spacer

Restricted benefit

Chronic obstructive pulmonary disease in patients unable to use this drug delivered from an oral pressurised inhalation device via a spacer

2000G NP	salbutamol 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules	2	5	..	*15.96	17.11	^a APO-Salbutamol	TX
							^a Asmol 2.5 uni-dose	AF
							^a Butamol 2.5	QA

RESPIRATORY SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
2001H NP	salbutamol 5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules	2	5	1.20 ..	*17.16 *16.44	17.11 17.59	^a GenRx Salbutamol	GX
							^a Pharmacor Salbutamol 2.5	CR
							^a Salbutamol Actavis	UA
							^a Salbutamol-GA	GN
							^a Salbutamol Sandoz	SZ
							^a Ventolin Nebules	GK
							^a APO-Salbutamol	TX
							^a Asmol 5 uni-dose	AF
							^a Butamol 5	QA
							^a GenRx Salbutamol	GX
							^a Pharmacor Salbutamol 5	CR
							^a Salbutamol Actavis	UA
							^a Salbutamol-GA	GN
							^a Salbutamol Sandoz	SZ
							^a Ventolin Nebules	GK

SALBUTAMOL

Restricted benefit

Patients unable to achieve co-ordinated use of other metered dose inhalers containing this drug

8354Q NP	salbutamol Oral pressurised inhalation in breath actuated device 100 micrograms (base) per dose (200 doses), CFC-free formulation, 1	2	5	..	*38.94	37.70	Airomir Autohaler	IA

SALMETEROL

Restricted benefit

Patients with frequent episodes of asthma who are currently receiving treatment with oral corticosteroids

Restricted benefit

Patients with frequent episodes of asthma who are currently receiving treatment with optimal doses of inhaled corticosteroids

8141L NP	salmeterol 50 microgram/actuation inhalation: powder for, 60 actuations	1	5	..	37.67	37.70	Serevent Accuhaler	GK

TERBUTALINE

2817G NP	terbutaline sulfate 500 microgram/actuation inhalation: powder for, 100 actuations	2	5	..	*18.20	19.35	Bricanyl Turbuhaler	AP

Adrenergics and other drugs for obstructive airway diseases

BUDESONIDE + EFORMOTEROL

Restricted benefit

Asthma

Clinical criteria:

Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR

Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR

Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist.

Population criteria:

Patient must be aged 12 years or over.

10015D NP	budesonide 100 microgram/actuation + eformoterol fumarate dihydrate 3 microgram/actuation inhalation: pressurised, 120 actuations	2	5	..	*59.10	37.70	Symbicort Rapihaler 100/3	AP
10024N NP	budesonide 50 microgram/actuation + eformoterol fumarate dihydrate 3 microgram/actuation inhalation: pressurised, 120 actuations	2	5	..	*54.80	37.70	Symbicort Rapihaler 50/3	AP

BUDESONIDE + EFORMOTEROL

Restricted benefit

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Asthma							
	Clinical criteria:							
	Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR							
	Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR							
	Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.							
	Population criteria:							
	Patient must be aged 12 years or over.							
8796Y NP	budesonide 100 microgram/actuation + eformoterol fumarate dihydrate 6 microgram/actuation inhalation: powder for, 120 actuations	1	5	..	54.81	37.70	Symbicort Turbuhaler 100/6	AP
8625Y NP	budesonide 200 microgram/actuation + eformoterol fumarate dihydrate 6 microgram/actuation inhalation: powder for, 120 actuations	1	5	..	59.11	37.70	Symbicort Turbuhaler 200/6	AP
	BUDESONIDE + EFORMOTEROL							
	<u>Restricted benefit</u>							
	Asthma							
	Clinical criteria:							
	Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.							
	Population criteria:							
	Patient must be aged 12 years or over.							
	<u>Note</u>							
	Unlike Symbicort Turbuhaler 200/6, Symbicort Rapihaler 200/6 is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy as the approved Product Information does not specify such use.							
	<u>Restricted benefit</u>							
	Chronic obstructive pulmonary disease (COPD)							
	Clinical criteria:							
	Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy,							
	AND							
	Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy,							
	AND							
	The treatment must be for symptomatic treatment.							
	<u>Note</u>							
	Patient must not be on a concomitant single agent long-acting beta-2 agonist.							
	<u>Note</u>							
	This product is not indicated for the initiation of bronchodilator therapy in COPD.							
10018G NP	budesonide 200 microgram/actuation + eformoterol fumarate dihydrate 6 microgram/actuation inhalation: pressurised, 120 actuations	2	5	..	*89.40	37.70	Symbicort Rapihaler 200/6	AP
	BUDESONIDE + EFORMOTEROL							
	<u>Restricted benefit</u>							
	Asthma							
	Clinical criteria:							
	Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.							
	Population criteria:							
	Patient must be aged 12 years or over.							
	<u>Note</u>							

RESPIRATORY SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Symbicort 400/12 is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.							
	<u>Restricted benefit</u>							
	Chronic obstructive pulmonary disease (COPD)							
	Clinical criteria:							
	Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy,							
	AND							
	Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy,							
	AND							
	The treatment must be for symptomatic treatment.							
	<u>Note</u>							
	Patient must not be on a concomitant single agent long-acting beta-2 agonist.							
	<u>Note</u>							
	This product is not indicated for the initiation of bronchodilator therapy in COPD.							
8750M NP	budesonide 400 microgram/actuation + eformoterol fumarate dihydrate 12 microgram/actuation inhalation: powder for, 120 actuations	1	5	..	89.37	37.70	Symbicort Turbuhaler 400/12	AP
	FLUTICASONE + EFORMOTEROL							
	<u>Restricted benefit</u>							
	Asthma							
	Clinical criteria:							
	Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.							
	Population criteria:							
	Patient must be aged 12 years or over.							
	<u>Note</u>							
	Flutiform is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.							
	<u>Note</u>							
	Flutiform is not indicated or PBS-subsidised for bronchodilator therapy in COPD.							
10007Q NP	fluticasone propionate 125 microgram/actuation + eformoterol fumarate dihydrate 5 microgram/actuation inhalation: pressurised, 120 actuations	1	5	..	53.03	37.70	flutiform 125/5	MF
10008R NP	fluticasone propionate 250 microgram/actuation + eformoterol fumarate dihydrate 10 microgram/actuation inhalation: pressurised, 120 actuations	1	5	..	73.01	37.70	flutiform 250/10	MF
2827T NP	fluticasone propionate 50 microgram/actuation + eformoterol fumarate dihydrate 5 microgram/actuation inhalation: pressurised, 120 actuations	1	5	..	43.18	37.70	flutiform 50/5	MF
	FLUTICASONE + SALMETEROL							
	<u>Restricted benefit</u>							
	Asthma							
	Clinical criteria:							
	Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids,							
	AND							
	Patient must have been stabilised on concomitant inhaled salmeterol xinafoate and fluticasone propionate if aged less than 12 years.							
8430Q NP	fluticasone propionate 100 microgram/actuation + salmeterol 50 microgram/actuation inhalation: powder for, 60 actuations	1	5	..	47.54	37.70	Seretide Accuhaler 100/50	GK

RESPIRATORY SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
8518H NP	fluticasone propionate 125 microgram/actuation + salmeterol 25 microgram/actuation inhalation: pressurised, 120 actuations	‡1	5	..	55.49	37.70	Seretide MDI 125/25	GK
8431R NP	fluticasone propionate 250 microgram/actuation + salmeterol 50 microgram/actuation inhalation: powder for, 60 actuations	‡1	5	..	55.49	37.70	Seretide Accuhaler 250/50	GK
8517G NP	fluticasone propionate 50 microgram/actuation + salmeterol 25 microgram/actuation inhalation: pressurised, 120 actuations	‡1	5	..	47.54	37.70	Seretide MDI 50/25	GK

FLUTICASONE + SALMETEROL

Restricted benefit

Asthma

Clinical criteria:

Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids,

AND

Patient must have been stabilised on concomitant inhaled salmeterol xinafoate and fluticasone propionate if aged less than 12 years.

Restricted benefit

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy,

AND

Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy,

AND

The treatment must be for symptomatic treatment.

Note

Patient must not be on a concomitant single agent long-acting beta-2 agonist.

Note

This product is not indicated for the initiation of bronchodilator therapy in COPD.

8519J NP	fluticasone propionate 250 microgram/actuation + salmeterol 25 microgram/actuation inhalation: pressurised, 120 actuations	‡1	5	..	72.63	37.70	Seretide MDI 250/25	GK
8432T NP	fluticasone propionate 500 microgram/actuation + salmeterol 50 microgram/actuation inhalation: powder for, 60 actuations	‡1	5	..	72.63	37.70	Seretide Accuhaler 500/50	GK

FLUTICASONE + VILANTEROL

Restricted benefit

Asthma

Clinical criteria:

Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:

Patient must be aged 12 years or over.

Note

This drug is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

Restricted benefit

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy,

AND

RESPIRATORY SYSTEM

[illegible]

RESPIRATORY SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	<u>Authority required (STREAMLINED)</u>							
	4655							
	Chronic obstructive pulmonary disease (COPD)							
	Clinical criteria:							
	Patient must have been stabilised on a combination of a long acting muscarinic antagonist and long acting beta-2 agonist.							
	<u>Note</u>							
	The treatment must not be used in combination with an ICS/LABA, or LAMA or LABA monotherapy.							
	<u>Note</u>							
	A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.							
	<u>Note</u>							
	A LABA includes indacaterol, salmeterol, eformoterol or vilanterol.							
	<u>Note</u>							
	This product is not PBS-subsidised for the treatment of asthma.							
	<u>Note</u>							
	This product is not indicated for the initiation of bronchodilator therapy in COPD.							
10188F NP	umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation inhalation: powder for, 30 actuations	\$1	5	..	96.38	37.70	Anoro Ellipta 62.5/25	GK

OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS

Glucocorticoids

BECLOMETHASONE

Restricted benefit

Patients unable to achieve co-ordinated use of other metered dose inhalers containing this drug

8409N NP	BECLOMETHASONE DIPROPIONATE Oral pressurised inhalation in breath actuated device 100 micrograms per dose (200 doses), CFC-free formulation, 1	\$1	5	..	39.47	37.70	Qvar 100 Autohaler	IA
8408M NP	BECLOMETHASONE DIPROPIONATE Oral pressurised inhalation in breath actuated device 50 micrograms per dose (200 doses), CFC-free formulation, 1	\$1	5	..	28.21	29.36	Qvar 50 Autohaler	IA
8407L NP	BECLOMETHASONE beclomethasone dipropionate 100 microgram/actuation inhalation: pressurised, 200	\$1	5	..	33.80	34.95	Qvar 100	IA
8406K NP	beclomethasone dipropionate 50 microgram/actuation inhalation: pressurised, 200	\$1	5	..	19.63	20.78	Qvar 50	IA

BUDESONIDE

Authority required (STREAMLINED)

1351

Severe chronic asthma in patients who require long-term steroid therapy and who are unable to use other forms of inhaled steroid therapy

2066R NP	budesonide 1 mg/2 mL inhalation: solution, 30 x 2 mL ampoules	\$1	5	..	49.34	37.70	Pulmicort Respules	AP
2065Q NP	budesonide 500 microgram/2 mL inhalation: solution, 30 x 2 mL ampoules	\$1	5	..	38.20	37.70	Pulmicort Respules	AP
2070Y	BUDESONIDE budesonide 100 microgram/actuation	\$1	5	..	23.68	24.83	Pulmicort Turbuhaler	AP

RESPIRATORY SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
NP	inhalation: powder for, 200 actuations							
2071B	budesonide 200 microgram/actuation	‡1	5	..	31.42	32.57	Pulmicort Turbuhaler	AP
NP	inhalation: powder for, 200 actuations							
2072C	budesonide 400 microgram/actuation	‡1	5	..	46.18	37.70	Pulmicort Turbuhaler	AP
NP	inhalation: powder for, 200 actuations							
CICLESONIDE								
8854B	ciclesonide 160 microgram/actuation	‡1	5	..	42.59	37.70	Alvesco 160	NQ
NP	inhalation: pressurised, 120 actuations							
8853Y	ciclesonide 80 microgram/actuation	‡1	5	..	26.49	27.64	Alvesco 80	NQ
NP	inhalation: pressurised, 120 actuations							
FLUTICASONE								
8147T	fluticasone propionate 100 microgram/actuation inhalation:	‡1	5	..	17.43	18.58	Flixotide Junior Accuhaler	GK
NP	powder for, 60 actuations							
8345F	fluticasone propionate 125 microgram/actuation inhalation:	‡1	5	..	31.00	32.15	Flixotide	GK
NP	pressurised, 120 actuations							
8148W	fluticasone propionate 250 microgram/actuation inhalation:	‡1	5	..	31.00	32.15	Flixotide Accuhaler	GK
NP	powder for, 60 actuations							
8346G	fluticasone propionate 250 microgram/actuation inhalation:	‡1	1	..	50.06	37.70	Flixotide	GK
NP	pressurised, 120 actuations							
8516F	fluticasone propionate 50 microgram/actuation inhalation:	‡1	5	..	17.43	18.58	Flixotide Junior	GK
NP	pressurised, 120							
8149X	fluticasone propionate 500 microgram/actuation inhalation:	‡1	1	..	50.06	37.70	Flixotide Accuhaler	GK
NP	powder for, 60 actuations							
Anticholinergics								
ACLIDINIUM								
<u>Restricted benefit</u>								
Chronic obstructive pulmonary disease (COPD)								
10124W	aclidinium 322 microgram/actuation	‡1	5	..	62.73	37.70	Bretaris Genuair	FK
NP	inhalation: powder for, 60 actuations							
GLYCOPYRRONIUM								
<u>Restricted benefit</u>								
Chronic obstructive pulmonary disease (COPD)								
10059K	glycopyrronium 50 microgram	1	5	..	62.73	37.70	seebri breezhaler	NV
NP	inhalation, 30 capsules							
IPRATROPIUM								
8671J	ipratropium bromide 20 microgram/actuation inhalation:	2	5	..	*34.18	35.33	Atrovent	BY
NP	pressurised, 200 actuations							
IPRATROPIUM								
<u>Restricted benefit</u>								
Asthma in patients unable to use this drug delivered from an oral pressurised inhalation device via a spacer								
<u>Restricted benefit</u>								
Chronic obstructive pulmonary disease in patients unable to use this drug delivered from an oral pressurised inhalation device via a spacer								
1542E	ipratropium bromide 250 microgram/mL inhalation: solution,	2	5	..	*28.28	29.43	^a Aeron 250	QA
NP	30 x 1 mL ampoules							
							^a APO-Ipratropium	TX
							^a Ipratrin	AF
				^b 0.52	*28.80	29.43	^a Atrovent	BY
8238N	ipratropium bromide 500 microgram/mL inhalation: solution,	2	5	..	*32.20	33.35	^a Aeron 500	QA
NP	30 x 1 mL ampoules							
							^a APO-Ipratropium	TX
							^a Ipratrin Adult	AF

RESPIRATORY SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
				^b 0.48	*32.68	33.35	^a Atrovent Adult	BY
TIOTROPIUM								
<u>Restricted benefit</u>								
Chronic obstructive pulmonary disease								
8626B NP	tiotropium 18 microgram inhalation: powder for, 30 capsules	1	5	..	62.73	37.70	Spiriva	BY
UMECLIDINIUM								
<u>Restricted benefit</u>								
Chronic obstructive pulmonary disease (COPD)								
10187E NP	umeclidinium 62.5 microgram/actuation inhalation: powder for, 30 actuations	1	5	..	62.73	37.70	Incruse Ellipta	GK
<i>Antiallergic agents, excl. corticosteroids</i>								
CROMOGLYCATE								
8767K NP	cromoglycate sodium 1 mg/actuation inhalation: pressurised, 200	1	5	..	33.84	34.99	Intal CFC-Free	SW
2878L NP	cromoglycate sodium 20 mg inhalation: powder for, 100 capsules	1	5	..	31.75	32.90	Intal Spincaps	GN
8334P NP	cromoglycate sodium 5 mg/actuation inhalation: pressurised, 112	1	5	..	38.65	37.70	Intal Forte CFC-Free	SW
NEDOCROMIL								
8365G NP	nedocromil sodium 2 mg/actuation inhalation: pressurised, 112 actuations	1	5	..	40.20	37.70	Tilade CFC-Free	SW
ADRENERGICS FOR SYSTEMIC USE								
<i>Alpha- and beta-adrenoreceptor agonists</i>								
ADRENALINE								
1016L NP	adrenaline 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules	1	1	..	20.68	21.83	Link Medical Products Pty Ltd	LM
5004J DP	adrenaline 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules	1	..	..	20.68	21.83	Link Medical Products Pty Ltd	LM
ADRENALINE								
<u>Authority required</u>								
Initial sole PBS-subsidised supply for anticipated emergency treatment of acute allergic reactions with anaphylaxis in a patient who has been assessed to be at significant risk of anaphylaxis by, or in consultation with, a clinical immunologist, allergist, paediatrician or respiratory physician. The name of the specialist consulted must be provided at the time of application for initial supply								
<u>Authority required</u>								
Initial sole PBS-subsidised supply for anticipated emergency treatment of acute allergic reactions with anaphylaxis in a patient who has been discharged from hospital or an emergency department after treatment with adrenaline for acute allergic reaction with anaphylaxis								
<u>Authority required</u>								
Continuing sole PBS-subsidised supply for anticipated emergency treatment of acute allergic reactions with anaphylaxis, where the patient has previously been issued with an authority prescription for this drug								
<u>Caution</u>								
EpiPen and Anapen products have different administration techniques and should not be prescribed to the same patient without training in their use.								
<u>Note</u>								
The auto-injector should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the auto-injector device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au .)								
<u>Note</u>								
Authority approvals will be limited to a maximum quantity of 2 auto-injectors (Anapen or EpiPen) at any one time.								
No repeats will be issued.								
3408J NP	adrenaline 150 microgram/0.3 mL injection, 1 x 0.3 mL syringe	1	..	..	106.34	37.70	Anapen Junior	LM
8697R NP	adrenaline 150 microgram/0.3 mL injection, 1 x 0.3 mL syringe	1	..	..	106.34	37.70	EpiPen Jr.	AL
3409K NP	adrenaline 300 microgram/0.3 mL injection, 1 x 0.3 mL syringe	1	..	..	106.34	37.70	Anapen	LM
8698T	adrenaline 300 microgram/0.3 mL	1	..	..	106.34	37.70	EpiPen	AL

RESPIRATORY SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

NP injection, 1 x 0.3 mL syringe

Selective beta-2-adrenoreceptor agonists

SALBUTAMOL

1103C	salbutamol 2 mg/5 mL oral liquid, 150 mL	2	5	..	*22.54	23.69	Ventolin	GK

NP

TERBUTALINE

1034K	terbutaline sulfate 500 microgram/mL injection, 5 x 1 mL ampoules	1	..	..	30.93	32.08	Bricanyl	AP

NP

OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

Xanthines

THEOPHYLLINE

Caution

Because of variable effects of food on absorption of sustained release theophylline preparations, patients stabilised on one brand should not be changed to another without appropriate monitoring.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2614N	theophylline 133.3 mg/25 mL oral liquid, 500 mL	\$1	5	..	12.65	13.80	Nuelin	IA
NP								
8230E	theophylline 200 mg tablet: modified release, 100 tablets	1	5	..	12.50	13.65	Nuelin-SR 200	IA
NP								
2634P	theophylline 250 mg tablet: modified release, 100 tablets	1	5	..	13.66	14.81	Nuelin-SR 250	IA
NP								
8231F	theophylline 300 mg tablet: modified release, 100 tablets	1	5	..	15.04	16.19	Nuelin-SR 300	IA
NP								

Leukotriene receptor antagonists

MONTELUKAST

Authority required (STREAMLINED)

2617

First-line preventer medication, as the single preventer agent for children aged 2 to 5 years with frequent intermittent or mild persistent asthma, as an alternative to sodium cromoglycate or nedocromil sodium

Note

Montelukast sodium is not PBS-subsidised for use in a child aged 2 to 5 years with moderate to severe asthma. It is not intended as an alternative for a child aged 2 to 5 years who requires a corticosteroid as a preventer medication.

Montelukast sodium is not subsidised in a child aged 2 to 5 years for use in combination with other preventer medications. PBS subsidy for montelukast sodium will therefore cease for a child aged 2 to 5 years who requires a preventer medication in addition to montelukast sodium.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

8627C	montelukast 4 mg tablet: chewable, 28	1	5	..	32.03	33.18	^a APO-Montelukast	TX
NP								
							^a Auro-Montelukast Tabs 4	DO
							^a Chem mart Montelukast	CH
							^a Lukair	FR
							^a Montair 4	GN
							^a Montelukast AN	EA
							^a Montelukast GH	GQ
							^a Montelukast RBX	RA
							^a Montelukast Sandoz 4	SZ
							^a Pharmacor Montelukast 4	CR
							^a Respikast 4	QA
							^a Singulair	MK
							^a Terry White Chemists Montelukast	TW
							^a T Lukast	AF

MONTELUKAST

Authority required (STREAMLINED)

RESPIRATORY SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
2618							
First-line preventer medication, as the single preventer agent for children aged 6 to 14 years with frequent intermittent or mild persistent asthma, as an alternative to sodium cromoglycate or nedocromil sodium							
Authority required (STREAMLINED)							
3217							
Prevention of exercise-induced asthma, as an alternative to adding salmeterol xinafoate or eformoterol fumarate, in a child aged 6 to 14 years whose asthma is otherwise well controlled while receiving optimal dose inhaled corticosteroid, but who requires short-acting beta-2 agonist 3 or more times per week for prevention or relief of residual exercise-related symptoms							
Note							
Montelukast sodium is not PBS-subsidised for use in a patient aged 15 years or older, or for use in addition to a long-acting beta-agonist in any age group, or for use as a single second line preventer, as an alternative to corticosteroids, in a child aged 6 to 14 years with moderate to severe asthma.							
Note							
No applications for increased maximum quantities and/or repeats will be authorised.							
8628D NP	montelukast 5 mg tablet: chewable, 28	1	5	..	30.51	31.66	a APO-Montelukast TX a Auro-Montelukast Tabs DO a Chem mart CH a Montelukast a Lukair FR a Montair 5 GN a Montelukast AN EA a Montelukast GH GQ a Montelukast RBX RA a Montelukast Sandoz 5 SZ a Pharmacor CR a Montelukast 5 a Respikast 5 QA a Singulair MK a Terry White Chemists TW a Montelukast a T Lukast AF

COUGH AND COLD PREPARATIONS

COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS

Opium alkaloids and derivatives

CODEINE

1214X NP	codeine phosphate 30 mg tablet, 20	1	..	..	17.21	18.36	Fawns and McAllan Proprietary Limited	FM

ANTI-HISTAMINES FOR SYSTEMIC USE

ANTI-HISTAMINES FOR SYSTEMIC USE

Phenothiazine derivatives

PROMETHAZINE

1948M NP	promethazine hydrochloride 50 mg/2 mL injection, 5 x 2 mL ampoules	2	..	..	*30.58	31.73	Hospira Pty Limited	HH

SENSORY ORGANS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

SENSORY ORGANS

OPHTHALMOLOGICALS

ANTIINFECTIVES

Antibiotics

AZITHROMYCIN

Restricted benefit

Trachoma

Note

No applications for increased maximum quantities and/or repeats will be authorised.

8201P NP	azithromycin 200 mg/5 mL oral liquid: powder for, 15 mL	1	..	..	#23.70	25.20	Zithromax	PF
8336R NP	azithromycin 500 mg tablet, 2	1	2	..	13.25	14.40	^a APO-Azithromycin	TX
							^a Azithromycin-GA	UA
							^a Azithromycin Sandoz	SZ
							^a Chem mart	CH
							^a Azithromycin	
							^a Terry White Chemists	TW
							^a Azithromycin	
							^a Zithromax	PF
							^a Zitrocin	GN

CHLORAMPHENICOL

2360F NP,MW	chloramphenicol 0.5% eye drops, 10 mL	1	2	..	11.34	12.49	Chlorsig	QA
5055C DP	chloramphenicol 0.5% eye drops, 10 mL	1	..	..	11.34	12.49	Chlorsig	QA
5512D OP	chloramphenicol 0.5% eye drops, 10 mL	1	2	..	11.34	12.49	Chlorsig	QA
1171P NP,MW	chloramphenicol 1% eye ointment, 4 g	1	..	..	10.10	11.25	Chlorsig	QA
5511C OP	chloramphenicol 1% eye ointment, 4 g	1	..	..	10.10	11.25	Chlorsig	QA

GENTAMICIN

Restricted benefit

Invasive ocular infection

Restricted benefit

Perioperative use in ophthalmic surgery

Restricted benefit

Suspected pseudomonal eye infection

1441W	gentamicin 0.3% eye drops, 5 mL	1	2	..	18.63	19.78	Genoptic	AG

GENTAMICIN

Restricted benefit

Perioperative use in ophthalmic surgery

Restricted benefit

Suspected pseudomonal eye infection

5566Y OP	gentamicin 0.3% eye drops, 5 mL	1	2	..	18.63	19.78	Genoptic	AG

TOBRAMYCIN

Restricted benefit

Invasive ocular infection

Restricted benefit

Perioperative use in ophthalmic surgery

Restricted benefit

Suspected pseudomonal eye infection

SENSORY ORGANS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
2328M	tobramycin 0.3% (3 mg/mL) eye drops, 5 mL	‡1	2	..	19.62	20.77	Tobrex	AQ
2329N	tobramycin 0.3% eye ointment, 3.5 g	‡1	..	..	22.72	23.87	Tobrex	AQ

TOBRAMYCIN

Restricted benefit

Perioperative use in ophthalmic surgery

Restricted benefit

Suspected pseudomonal eye infection

5569D OP	tobramycin 0.3% (3 mg/mL) eye drops, 5 mL	‡1	2	..	19.62	20.77	Tobrex	AQ

5570E OP	tobramycin 0.3% eye ointment, 3.5 g	‡1	..	..	22.72	23.87	Tobrex	AQ

Antivirals

ACICLOVIR

Restricted benefit

Herpes simplex keratitis

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1002R NP	aciclovir 3% eye ointment, 4.5 g	‡1	..	..	37.80	37.70	Zovirax	GK

ACICLOVIR

Restricted benefit

Herpes simplex keratitis

5501M OP	aciclovir 3% eye ointment, 4.5 g	‡1	..	..	37.80	37.70	Zovirax	GK

Fluoroquinolones

CIPROFLOXACIN

Authority required

Bacterial keratitis

Treatment criteria:

Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

1217C	ciprofloxacin 0.3% eye drops, 5 mL	2	..	..	*28.82	29.97	^a CiloQuin	IQ
				^b 2.06	*30.88	29.97	^a Ciloxan	AQ

CIPROFLOXACIN

Authority required

Bacterial keratitis

Treatment criteria:

Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

5564W OP	ciprofloxacin 0.3% eye drops, 5 mL	2	..	..	*28.82	29.97	^a CiloQuin	IQ
				^b 2.06	*30.88	29.97	^a Ciloxan	AQ

OFLOXACIN

Authority required

Bacterial keratitis

Treatment criteria:

Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

5567B OP	ofloxacin 0.3% (3 mg/mL) eye drops, 5 mL	2	..	..	*35.64	36.79	Ocuflox	AG

OFLOXACIN

Authority required

Bacterial keratitis

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Treatment criteria:							
	Must be treated by an ophthalmologist or in consultation with an ophthalmologist.							
8383F	ofloxacin 0.3% (3 mg/mL) eye drops, 5 mL	2	..	..	*35.64	36.79	Ocuflox	AG
ANTIINFLAMMATORY AGENTS								
Corticosteroids, plain								
	DEXAMETHASONE							
1288T NP	DEXAMETHASONE Eye drops 1 mg per mL (0.1%), 5 mL, 1	1	2	..	10.95	12.10	Maxidex	AQ
	DEXAMETHASONE							
	Note							
	No applications for increased maximum quantities and/or repeats will be authorised.							
5565X OP	DEXAMETHASONE Eye drops 1 mg per mL (0.1%), 5 mL, 1	1	..	..	10.95	12.10	Maxidex	AQ
	FLUOROMETHOLONE							
1204J NP	fluorometholone 0.1% eye drops, 5 mL	1	5	..	10.95	12.10	Flucon	AQ
							FML Liquifilm	AG
	FLUOROMETHOLONE							
	Note							
	No applications for increased maximum quantities and/or repeats will be authorised.							
5513E OP	fluorometholone 0.1% eye drops, 5 mL	1	..	..	10.95	12.10	Flucon	AQ
							FML Liquifilm	AG
	FLUOROMETHOLONE ACETATE							
1438Q NP	fluorometholone acetate 0.1% eye drops, 5 mL	1	2	..	10.95	12.10	Flarex	AQ
	FLUOROMETHOLONE ACETATE							
	Note							
	No applications for increased maximum quantities and/or repeats will be authorised.							
5533F OP	fluorometholone acetate 0.1% eye drops, 5 mL	1	..	..	10.95	12.10	Flarex	AQ
	HYDROCORTISONE ACETATE							
2441L NP	hydrocortisone acetate 1% eye ointment, 5 g	1	..	..	13.03	14.18	Hycor	QA
	HYDROCORTISONE ACETATE							
	Note							
	No applications for increased maximum quantities and/or repeats will be authorised.							
5516H OP	hydrocortisone acetate 1% eye ointment, 5 g	1	..	..	13.03	14.18	Hycor	QA
Corticosteroids and mydriatics in combination								
	PHENYLEPHRINE + PREDNISOLONE ACETATE							
	Restricted benefit							
	Corneal grafts							
	Restricted benefit							
	Uveitis							
3112T NP	phenylephrine hydrochloride 0.12% + prednisolone acetate 1% eye drops, 10 mL	1	2	..	26.16	27.31	Prednefrin Forte	AG
	PHENYLEPHRINE + PREDNISOLONE ACETATE							
	Restricted benefit							
	Uveitis							
	Note							
	No applications for increased maximum quantities and/or repeats will be authorised.							

SENSORY ORGANS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
5568C OP	phenylephrine hydrochloride 0.12% + prednisolone acetate 1% eye drops, 10 mL	‡1	..	..	26.16	27.31	Prednefrin Forte	AG

Antiinflammatory agents, non-steroids

FLURBIPROFEN

5514F OP	flurbiprofen sodium 0.03% (120 microgram/0.4 mL) eye drops, 5 x 0.4 mL ampoules	1	..	..	17.16	18.31	Ocufen	AG
8699W NP	flurbiprofen sodium 0.03% (120 microgram/0.4 mL) eye drops, 5 x 0.4 mL ampoules	1	..	..	17.16	18.31	Ocufen	AG

ANTIGLAUCOMA PREPARATIONS AND MIOTICS

Sympathomimetics in glaucoma therapy

APRACLONIDINE

Restricted benefit

Short-term reduction of intra-ocular pressure in patients already on maximally tolerated anti-glaucoma therapy

8083K	apraclonidine 0.5% eye drops, 10 mL	‡1	2	..	42.11	37.70	Iopidine 0.5%	AQ

BRIMONIDINE

5298W	brimonidine tartrate 0.15% eye drops, 5 mL	‡1	5	..	20.48	21.63	Alphagan P 1.5	AG
8351M	brimonidine tartrate 0.2% eye drops, 5 mL	‡1	5	..	20.48	21.63	^a Enidin	PE
				^B 1.63	22.11	21.63	^a Alphagan	AG

BRIMONIDINE

Note

Shared Care Model:

For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.

5563T OP	brimonidine tartrate 0.15% eye drops, 5 mL	‡1	5	..	20.48	21.63	Alphagan P 1.5	AG
5534G OP	brimonidine tartrate 0.2% eye drops, 5 mL	‡1	5	..	20.48	21.63	^a Enidin	PE
				^B 1.63	22.11	21.63	^a Alphagan	AG

BRIMONIDINE + TIMOLOL

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

The condition must have been inadequately controlled with monotherapy,

AND

Patient must have open-angle glaucoma; OR

Patient must have ocular hypertension.

Note

Shared Care Model:

For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.

5535H OP	brimonidine tartrate 0.2% + timolol 0.5% eye drops, 5 mL	‡1	5	..	26.37	27.52	Combigan	AG

BRIMONIDINE + TIMOLOL

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

The condition must have been inadequately controlled with monotherapy,

AND

Patient must have open-angle glaucoma; OR

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Patient must have ocular hypertension.							
8826M	brimonidine tartrate 0.2% + timolol 0.5% eye drops, 5 mL	±1	5	..	26.37	27.52	Combigan	AG
Parasympathomimetics								
PILOCARPINE								
2595N	pilocarpine hydrochloride 1% eye drops, 15 mL	±1	5	..	12.87	14.02	Isopto Carpine	AQ
2596P	pilocarpine hydrochloride 2% eye drops, 15 mL	±1	5	..	14.12	15.27	Isopto Carpine	AQ
2598R	pilocarpine hydrochloride 4% eye drops, 15 mL	±1	5	..	16.97	18.12	Isopto Carpine	AQ
PILOCARPINE								
Note								
Shared Care Model:								
For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.								
5536J OP	pilocarpine hydrochloride 1% eye drops, 15 mL	±1	5	..	12.87	14.02	Isopto Carpine	AQ
5537K OP	pilocarpine hydrochloride 2% eye drops, 15 mL	±1	5	..	14.12	15.27	Isopto Carpine	AQ
5538L OP	pilocarpine hydrochloride 4% eye drops, 15 mL	±1	5	..	16.97	18.12	Isopto Carpine	AQ
Carbonic anhydrase inhibitors								
ACETAZOLAMIDE								
Note								
Continuing Therapy Only:								
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
1004W NP	acetazolamide 250 mg tablet, 100	1	3	..	24.13	25.28	Diamox	QA
BRINZOLAMIDE								
Note								
Shared Care Model:								
For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.								
5540N OP	brinzolamide 1% eye drops, 5 mL	±1	5	..	23.11	24.26 ^a	BrinzoQuin	IQ
				^b 1.18	24.29	24.26 ^a	Azopt	AQ
BRINZOLAMIDE								
8483L	brinzolamide 1% eye drops, 5 mL	±1	5	..	23.11	24.26 ^a	BrinzoQuin	IQ
				^b 1.18	24.29	24.26 ^a	Azopt	AQ
BRINZOLAMIDE + TIMOLOL								
Restricted benefit								
Elevated intra-ocular pressure								
Clinical criteria:								
The condition must have been inadequately controlled with monotherapy,								
AND								
Patient must have open-angle glaucoma; OR								
Patient must have ocular hypertension.								
3438Y	brinzolamide 1% + timolol 0.5% eye drops, 5 mL	±1	5	..	27.22	28.37	Azarga	AQ
BRINZOLAMIDE + TIMOLOL								
Restricted benefit								
Elevated intra-ocular pressure								

SENSORY ORGANS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
Clinical criteria:								
The condition must have been inadequately controlled with monotherapy,								
AND								
Patient must have open-angle glaucoma; OR								
Patient must have ocular hypertension.								
Note								
Shared Care Model:								
For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.								
5562R OP	brinzolamide 1% + timolol 0.5% eye drops, 5 mL	£1	5	..	27.22	28.37	Azarga	AQ
DORZOLAMIDE								
Note								
Shared Care Model:								
For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.								
5541P OP	dorzolamide 2% (20 mg/mL) eye drops, 5 mL	£1	5	..	19.26	20.41	^a Trusamide	QA
							^a Trusopt	MK
DORZOLAMIDE								
8488R	dorzolamide 2% (20 mg/mL) eye drops, 5 mL	£1	5	..	19.26	20.41	^a Trusamide	QA
							^a Trusopt	MK
DORZOLAMIDE + TIMOLOL								
Restricted benefit								
Elevated intra-ocular pressure								
Clinical criteria:								
The condition must have been inadequately controlled with monotherapy,								
AND								
Patient must have open-angle glaucoma; OR								
Patient must have ocular hypertension.								
Note								
Shared Care Model:								
For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.								
5542Q OP	dorzolamide 2% + timolol 0.5% eye drops, 5 mL	£1	5	..	24.19	25.34	^a Cosdor	QA
							^a Cosopt	MK
							^a Dorzolamide/Timolol Sandoz 20/5	SZ
DORZOLAMIDE + TIMOLOL								
Restricted benefit								
Elevated intra-ocular pressure								
Clinical criteria:								
The condition must have been inadequately controlled with monotherapy,								
AND								
Patient must have open-angle glaucoma; OR								
Patient must have ocular hypertension.								
8567X	dorzolamide 2% + timolol 0.5% eye drops, 5 mL	£1	5	..	24.19	25.34	^a Cosdor	QA
							^a Cosopt	MK
							^a Dorzolamide/Timolol Sandoz 20/5	SZ

Beta blocking agents

Prostaglandin analogues

BIMATOPROST

Note

Shared Care Model:

For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.

5551E OP	bimatoprost 0.03% eye drops, 3 mL	#1	5	..	42.48	37.70	Lumigan	AG
10053D OP	bimatoprost 0.03% eye drops, 30 x 0.4 mL unit doses	#1	5	..	36.91	37.70	Lumigan PF	AG

BIMATOPROST

8620Q	bimatoprost 0.03% eye drops, 3 mL	£1	5	..	42.48	37.70	Lumigan	AG
10046R	bimatoprost 0.03% eye drops, 30 x 0.4 mL unit doses	£1	5	..	36.91	37.70	Lumigan PF	AG

BIMATOPROST + TIMOLOL

Restricted benefit

Elevated intra-ocular pressure

SENSORY ORGANS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
Clinical criteria: The condition must have been inadequately controlled with monotherapy, AND Patient must have open-angle glaucoma; OR Patient must have ocular hypertension.								
Note Shared Care Model: For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.								
5558M OP	bimatoprost 0.03% + timolol 0.5% eye drops, 3 mL	1	5	..	46.94	37.70	Ganfort 0.3/5	AG
10108B OP	bimatoprost 0.03% + timolol 0.5% eye drops, 30 x 0.4 mL unit doses	1	5	..	41.21	37.70	GANfort PF 0.3/5	AG
BIMATOPROST + TIMOLOL Restricted benefit Elevated intra-ocular pressure Clinical criteria: The condition must have been inadequately controlled with monotherapy, AND Patient must have open-angle glaucoma; OR Patient must have ocular hypertension.								
9464D	bimatoprost 0.03% + timolol 0.5% eye drops, 3 mL	1	5	..	46.94	37.70	Ganfort 0.3/5	AG
BIMATOPROST + TIMOLOL Restricted benefit Elevated intra-ocular pressure Clinical criteria: The condition must have been inadequately controlled with monotherapy, AND Patient must have open-angle glaucoma; OR Patient must have ocular hypertension.								
10107Y	bimatoprost 0.03% + timolol 0.5% eye drops, 30 x 0.4 mL unit doses	1	5	..	41.21	37.70	GANfort PF 0.3/5	AG
LATANOPROST Note Shared Care Model: For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.								
5552F OP	latanoprost 0.005% eye drops, 2.5 mL	1	5	..	24.06	25.21	^a APO-Latanoprost	TX
							^a Chem mart Latanoprost	CH
							^a Latanoprost Actavis	GN
							^a Latanoprost GH	GQ
							^a Latanoprost Pfizer	FZ
							^a Latanoprost Sandoz	SZ
							^a Terry White Chemists Latanoprost	TW
							^a Xalaprost	QA
							^a Xalatan	PF
LATANOPROST								
8243W	latanoprost 0.005% eye drops, 2.5 mL	1	5	..	24.06	25.21	^a APO-Latanoprost	TX
							^a Chem mart Latanoprost	CH
							^a Latanoprost Actavis	GN
							^a Latanoprost GH	GQ

SENSORY ORGANS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							a Latanoprost Pfizer	FZ
							a Latanoprost Sandoz	SZ
							a Terry White Chemists Latanoprost	TW
							a Xalaprost	QA
							a Xalatan	PF

LATANOPROST + TIMOLOL

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

The condition must have been inadequately controlled with monotherapy,

AND

Patient must have open-angle glaucoma; OR

Patient must have ocular hypertension.

Note

Shared Care Model:

For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.

5553G OP	latanoprost 0.005% + timolol 0.5% eye drops, 2.5 mL	£1	5	..	41.21	37.70	a APO- Latanoprost/Timolol 0.05/5	TX
							a Latanocom	FZ
							a Latanoprost/Timolol Sandoz 50/5	SZ
							a Xalacom	PF
							a Xalamol 50/5	QA

LATANOPROST + TIMOLOL

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

The condition must have been inadequately controlled with monotherapy,

AND

Patient must have open-angle glaucoma; OR

Patient must have ocular hypertension.

8895E	latanoprost 0.005% + timolol 0.5% eye drops, 2.5 mL	£1	5	..	41.21	37.70	a APO- Latanoprost/Timolol 0.05/5	TX
							a Latanocom	FZ
							a Latanoprost/Timolol Sandoz 50/5	SZ
							a Xalacom	PF
							a Xalamol 50/5	QA

T AFLUPROST

Note

Shared Care Model:

For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.

2748P OP	tafluprost 0.0015% eye drops, 30 x 0.3 mL unit doses	£1	5	..	34.16	35.31	Saflutan	MK

T AFLUPROST

2755B	tafluprost 0.0015% eye drops, 30 x 0.3 mL unit doses	£1	5	..	34.16	35.31	Saflutan	MK

TIMOLOL + TRAVOPROST

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

SENSORY ORGANS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
The condition must have been inadequately controlled with monotherapy, AND Patient must have open-angle glaucoma; OR Patient must have ocular hypertension. Note Shared Care Model: For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.								
5555J OP	timolol 0.5% + travoprost 0.004% eye drops, 2.5 mL	£1	5	..	46.94	37.70	Duotrav	AQ
TIMOLOL + TRAVOPROST Restricted benefit Elevated intra-ocular pressure Clinical criteria: The condition must have been inadequately controlled with monotherapy, AND Patient must have open-angle glaucoma; OR Patient must have ocular hypertension.								
9057Q	timolol 0.5% + travoprost 0.004% eye drops, 2.5 mL	£1	5	..	46.94	37.70	Duotrav	AQ
TRAVOPROST Note Shared Care Model: For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.								
5554H OP	travoprost 0.004% (40 microgram/mL) eye drops, 2.5 mL	£1	5	..	42.48	37.70	Travatan	AQ
8597L	travoprost 0.004% (40 microgram/mL) eye drops, 2.5 mL	£1	5	..	42.48	37.70	Travatan	AQ
MYDRIATICS AND CYCLOPLEGICS Anticholinergics								
ATROPINE								
1093M NP	ATROPINE Eye drops containing atropine sulfate 10 mg per mL (1%), 15 mL, 1	£1	2	..	22.11	23.26	Atropt	QA
HOMATROPINE								
10063P OP	homatropine hydrobromide 2% eye drops, 15 mL	£1	2	..	19.15	20.30	Isopto Homatropine	AQ
2541R NP	homatropine hydrobromide 2% eye drops, 15 mL	£1	2	..	19.15	20.30	Isopto Homatropine	AQ
DECONGESTANTS AND ANTIALLERGICS Other antiallergics								
CROMOGLYCATE Restricted benefit Vernal kerato-conjunctivitis								
1127H NP	cromoglycate sodium 2% eye drops, 10 mL	£1	5	..	14.55	15.70	Opticrom	SW
5529B OP	cromoglycate sodium 2% eye drops, 10 mL	£1	5	..	14.55	15.70	Opticrom	SW

OCULAR VASCULAR DISORDER AGENTS

Antineovascularisation agents

AFLIBERCEPT

Authority required

SENSORY ORGANS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	Subfoveal choroidal neovascularisation (CNV)						
	Treatment Phase: Initial treatment						
	Clinical criteria:						
	The condition must be due to age-related macular degeneration (AMD),						
	AND						
	The condition must be diagnosed by fluorescein angiography,						
	AND						
	The treatment must be the sole PBS-subsidised therapy for this condition.						
	Treatment criteria:						
	Must be treated by an ophthalmologist.						
	Authority approval for initial treatment of each eye must be sought.						
	The first authority application for each eye must be made in writing or by telephone.						
	A written application must include:						
	a) a completed authority prescription form;						
	b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form; and						
	c) a copy of the fluorescein angiogram.						
	A telephone application must be made following submission by facsimile of a copy of a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the fluorescein angiogram. The original documentation must be submitted to the Chief Executive Medicare by post after the application has been authorised.						
	Where a fluorescein angiogram cannot be performed due to a contraindication as listed in the TGA-approved product information, details of the contraindication must be provided. A copy of the report of an alternative method of diagnosis must be included in the application, for example, optical coherence tomography (OCT) or red free photography.						
	Note						
	The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.						
	Note						
	Authority approvals will be administered by the Complex Drugs Unit of the Department of Human Services.						
	Note						
	Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).						
	Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au						
	Applications for authority to prescribe should be forwarded to:						
	Department of Human Services						
	Prior Written Approval of Complex Drugs						
	Reply Paid 9826						
	GPO Box 9826						
	HOBART TAS 7001						
	Note						
	Special Pricing Arrangements apply.						
	Authority required						
	Subfoveal choroidal neovascularisation (CNV)						
	Treatment Phase: Continuing treatment						
	Clinical criteria:						
	The condition must be due to age-related macular degeneration (AMD),						
	AND						
	The treatment must be the sole PBS-subsidised therapy for this condition,						
	AND						
	Patient must have previously been granted an authority prescription for the same eye.						
	Treatment criteria:						
	Must be treated by an ophthalmologist.						
	Note						
	Authority approvals will be administered by the Complex Drugs Unit of the Department of Human Services.						

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	Note Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Note No increase in the maximum number of repeats may be authorised. Note Special Pricing Arrangements apply.						
2168D	afibercept 4 mg/0.1 mL injection, 1 x 0.1 mL vial	1	2	..	1431.50	37.70	Eylea BN
	RANIBIZUMAB Authority required Subfoveal choroidal neovascularisation (CNV) Treatment Phase: Initial treatment Clinical criteria: The condition must be due to age-related macular degeneration (AMD), AND The condition must be diagnosed by fluorescein angiography, AND The treatment must be the sole PBS-subsidised therapy for this condition. Treatment criteria: Must be treated by an ophthalmologist. Authority approval for initial treatment of each eye must be sought. The first authority application for each eye must be made in writing or by telephone. A written application must include: a) a completed authority prescription form; b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form; and c) a copy of the fluorescein angiogram. A telephone application must be made following submission by facsimile of a copy of a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the fluorescein angiogram. The original documentation must be submitted to the Chief Executive Medicare by post after the application has been authorised. Where a fluorescein angiogram cannot be performed due to a contraindication as listed in the TGA-approved product information, details of the contraindication must be provided. A copy of the report of an alternative method of diagnosis must be included in the application, for example, optical coherence tomography (OCT) or red free photography. Note The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone. Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 Note Special Pricing Arrangements apply. Note Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution. Authority required						

SENSORY ORGANS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Subfoveal choroidal neovascularisation (CNV)							
	Treatment Phase: Continuing treatment							
	Clinical criteria:							
	The condition must be due to age-related macular degeneration (AMD),							
	AND							
	The treatment must be the sole PBS-subsidised therapy for this condition,							
	AND							
	Patient must have previously been granted an authority prescription for the same eye.							
	Treatment criteria:							
	Must be treated by an ophthalmologist.							
	Note							
	Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).							
	Note							
	Special Pricing Arrangements apply.							
	Note							
	Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.							
10138N	ranibizumab 1.65 mg/0.165 mL injection, 1 x 0.165 mL syringe	1	2	..	1431.50	37.70	^a Lucentis	NV
1382R	ranibizumab 2.3 mg/0.23 mL injection, 1 x 0.23 mL vial	1	2	..	1431.50	37.70	^a Lucentis	NV

VERTEPORFIN

Authority required

Initial treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of predominantly (greater than or equal to 50%) classic, subfoveal choroidal neovascularisation (CNV) due to age-related macular degeneration (AMD), as diagnosed by fluorescein angiography, in a patient with a baseline visual acuity equal to or better than 6/60 (20/200).

Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia.

The first authority application for each eye must be made in writing, and must include:

- (a) a completed authority prescription form; and
- (b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form [www.medicareaustralia.gov.au]; and
- (c) a copy of the fluorescein angiogram demonstrating that the CNV is predominantly classic (greater than or equal to 50%).

Written applications for authority to prescribe verteporfin should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Alternatively, the first authority application may be faxed to Medicare Australia on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Medicare Australia will then contact the prescriber by telephone. The original documentation must be posted to the above address after approval has been gained.

No more than 15 treatments (1 initial and 14 continuing) per eye will be authorised.

Medicare Australia should be notified if treatment is abandoned prior to completion of the laser activation step but after infusion of verteporfin. Telephone 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The reason treatment is abandoned must be provided. Where such notification has been made, the treatment so affected will not count towards the maximum

Authority required

Initial PBS-subsidised treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of predominantly (greater than or equal to 50%) classic, subfoveal choroidal neovascularisation (CNV) due to macular degeneration where the patient has been authorised by the Angiogram Review Panel to receive treatment with verteporfin in the same eye under the MBS Visudyne Therapy Program.

Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia.

The first authority application for each eye must be made in writing, and must include:

- (a) a completed authority prescription form; and
- (b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form [www.medicareaustralia.gov.au], which includes

SENSORY ORGANS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	the date of review by the Angiogram Review Panel and the number of treatments administered in that eye under the MBS Visudyne Therapy Program; and (c) a copy of the fluorescein angiogram demonstrating that the CNV is predominantly classic (greater than or equal to 50%). Written applications for authority to prescribe verteporfin should be forwarded to: Medicare Australia Prior Written Approval of Specialised Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 Alternatively, the first authority application may be faxed to Medicare Australia on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Medicare Australia will then contact the prescriber by telephone. The original documentation must be posted to the above address after approval has been gained. A patient is eligible for a total of 15 subsidised treatments per eye. This maximum includes treatments administered under the MBS Visudyne Therapy Program and the PBS. Medicare Australia should be notified if treatment is abandoned prior to completion of the laser activation step but after infusion of verteporfin. Telephone 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The reason treatment is abandoned must be provided. Where such notification has been made, the treatment so affected will not count towards the maximum <u>Authority required</u> Continuing treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of predominantly (greater than or equal to 50%) classic, subfoveal choroidal neovascularisation (CNV) due to macular degeneration where the patient has previously been granted an authority prescription for the same eye. A patient is eligible for a total of 15 subsidised treatments per eye. This maximum includes treatments administered under the MBS Visudyne Therapy Program and the PBS. Medicare Australia should be notified if treatment is abandoned prior to completion of the laser activation step but after infusion of verteporfin. Telephone 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The reason treatment is abandoned must be provided. Where such notification has been made, the treatment so affected will not count towards the maximum. Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia. Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)						
1349B	verteporfin 15 mg injection, 1 x 15 mg vial	1	..	..	2246.70	37.70	Visudyne NV

OTHER OPHTHALMOLOGICALS

Other ophthalmologicals

CARBOMER-974

Authority required

Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

5502N OP	carbomer-974 0.3% eye gel, 30 x 500 mg unit doses	3	5	..	*36.40	37.55	Poly Gel	AQ

CARBOMER-974

Authority required (STREAMLINED)

1359

Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

8514D NP	carbomer-974 0.3% eye gel, 30 x 500 mg unit doses	3	5	..	*36.40	37.55	Poly Gel	AQ

CARBOMER-980

Authority required

Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

5504Q OP	carbomer-980 0.2% (2 mg/g) eye drops, 30 x 0.6 mL unit doses	3	5	..	*36.43	37.58	Viscotears Gel PF	AQ

CARBOMER-980

Authority required (STREAMLINED)

1359

Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

8578L NP	carbomer-980 0.2% (2 mg/g) eye drops, 30 x 0.6 mL unit doses	3	5	..	*36.43	37.58	Viscotears Gel PF	AQ

CARBOMER-980

Restricted benefit

SENSORY ORGANS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
Severe dry eye syndrome, including Sjogren's syndrome								
5503P OP	carbomer-980 0.2% eye gel, 10 g	‡1	5	..	10.00	11.15	^a Optifresh eye gel	PP
				^B 1.84	11.84	11.15	^a PAA	IQ
8384G NP	carbomer-980 0.2% eye gel, 10 g	‡1	5	..	10.00	11.15	^a Viscotears	AQ
				^B 1.84	11.84	11.15	^a Optifresh eye gel	PP
							^a PAA	IQ
							^a Viscotears	AQ

CARBOMER-980

Restricted benefit

For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

Note

No applications for increased maximum quantities and/or repeats will be authorised.

9210R	carbomer-980 0.2% eye gel, 10 g	‡1	11	..	10.00	11.15	^a Optifresh eye gel	PP
				^B 1.84	11.84	11.15	^a PAA	IQ
							^a Viscotears	AQ

CARMELLOSE SODIUM

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

5508X OP	carmellose sodium 1% (10 mg/mL) eye drops, 15 mL	‡1	5	..	10.93	12.08	Refresh Liquigel	AG
8593G NP	carmellose sodium 1% (10 mg/mL) eye drops, 15 mL	‡1	5	..	10.93	12.08	Refresh Liquigel	AG
5507W OP	carmellose sodium 0.5% (5 mg/mL) eye drops, 15 mL	‡1	5	..	10.93	12.08	Refresh Tears Plus	AG
8548X NP	carmellose sodium 0.5% (5 mg/mL) eye drops, 15 mL	‡1	5	..	10.93	12.08	Refresh Tears Plus	AG

CARMELLOSE SODIUM

Restricted benefit

For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

Note

No applications for increased maximum quantities and/or repeats will be authorised.

9212W	carmellose sodium 1% (10 mg/mL) eye drops, 15 mL	‡1	11	..	10.93	12.08	Refresh Liquigel	AG
9211T	carmellose sodium 0.5% (5 mg/mL) eye drops, 15 mL	‡1	11	..	10.93	12.08	Refresh Tears Plus	AG

CARMELLOSE SODIUM

Authority required (STREAMLINED)

1359

Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

2324H NP	carmellose sodium 1% (4 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses	3	5	..	*31.63	32.78	^a Optifresh Plus	PP
				^B 4.77	*36.40	32.78	^a Celluvisc	AG
8823J NP	carmellose sodium 0.25% (1.5 mg/0.6 mL) eye drops, 24 x 0.6 mL unit doses	4	5	..	*40.76	37.70	TheraTears	CX
2338C NP	carmellose sodium 0.5% (2 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses	3	5	..	*31.63	32.78	^a Optifresh Tears	PP
				^B 4.77	*36.40	32.78	^a Cellufresh	AG
8824K NP	carmellose sodium 1% (6 mg/0.6 mL) eye gel, 28 x 0.6 mL unit doses	3	5	..	*34.42	35.57	TheraTears	CX

CARMELLOSE SODIUM

Authority required

Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

5505R OP	carmellose sodium 1% (4 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses	3	5	..	*31.63	32.78	^a Optifresh Plus	PP
				^B 4.77	*36.40	32.78	^a Celluvisc	AG

SENSORY ORGANS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
5509Y OP	carmellose sodium 0.25% (1.5 mg/0.6 mL) eye drops, 24 x 0.6 mL unit doses	4	5	..	*40.76	37.70	TheraTears	CX
5506T OP	carmellose sodium 0.5% (2 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses	3	5	.. ^B 4.77	*31.63 *36.40	32.78	^a Optifresh Tears	PP
5510B OP	carmellose sodium 1% (6 mg/0.6 mL) eye gel, 28 x 0.6 mL unit doses	3	5	..	*34.42	35.57	^a Cellufresh TheraTears	AG CX

CARMELLOSE SODIUM + GLYCEROL

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

Note

The in-use shelf life of Optive is 6 months from the date of opening.

5556K OP	carmellose sodium 0.5% + glycerol 0.9% eye drops, 15 mL	‡1	3	..	10.93	12.08	Optive	AG
9355J NP	carmellose sodium 0.5% + glycerol 0.9% eye drops, 15 mL	‡1	3	..	10.93	12.08	Optive	AG

CARMELLOSE SODIUM + GLYCEROL

Restricted benefit

For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

Note

No applications for increased maximum quantities and/or repeats will be authorised.

Note

The in-use shelf life of Optive is 6 months from the date of opening.

9356K	carmellose sodium 0.5% + glycerol 0.9% eye drops, 15 mL	‡1	7	..	10.93	12.08	Optive	AG

CARMELLOSE SODIUM + GLYCEROL

Authority required

Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

5561Q OP	carmellose sodium 0.5% + glycerol 0.9% eye drops, 30 x 0.4 mL unit doses	3	5	..	*36.40	37.55	Optive	AG

CARMELLOSE SODIUM + GLYCEROL

Authority required (STREAMLINED)

1359

Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

9307W NP	carmellose sodium 0.5% + glycerol 0.9% eye drops, 30 x 0.4 mL unit doses	3	5	..	*36.40	37.55	Optive	AG

DEXTRAN-70 + HYPROMELLOSE

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

1509K NP	dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL	‡1	5	..	10.83	11.98	^a Poly-Tears	IQ
				^B 2.04	12.87	11.98	^a Tears Naturale	AQ
5520M OP	dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL	‡1	5	..	10.83	11.98	^a Poly-Tears	IQ
				^B 2.04	12.87	11.98	^a Tears Naturale	AQ

DEXTRAN-70 + HYPROMELLOSE

Restricted benefit

For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

Note

No applications for increased maximum quantities and/or repeats will be authorised.

9216C	dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL	‡1	11	..	10.83	11.98	^a Poly-Tears	IQ
				^B 2.04	12.87	11.98	^a Tears Naturale	AQ

DEXTRAN-70 + HYPROMELLOSE

Authority required

SENSORY ORGANS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops								
5521N OP	dextran-70 0.1% + hypromellose 0.3% eye drops, 28 x 0.4 mL unit doses	3	5	..	*35.41	36.56	Bion Tears	AQ
DEXTRAN-70 + HYPROMELLOSE								
<u>Authority required (STREAMLINED)</u>								
1359								
Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops								
8299T NP	dextran-70 0.1% + hypromellose 0.3% eye drops, 28 x 0.4 mL unit doses	3	5	..	*35.41	36.56	Bion Tears	AQ
HYPROMELLOSE								
<u>Restricted benefit</u>								
Severe dry eye syndrome, including Sjogren's syndrome								
5518K OP	HYPROMELLOSE Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative), 1	1	5	..	10.61	11.76	^a In a Wink Moisturising	IQ
8287E NP	HYPROMELLOSE Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative), 1	1	5	^B 1.95	12.56	11.76	^a Genteal	AQ
				..	10.61	11.76	^a In a Wink Moisturising	IQ
2956N NP	HYPROMELLOSE Eye drops 5 mg per mL (0.5%), 15 mL, 1	1	5	^B 1.95	12.56	11.76	^a Genteal	AQ
				..	10.61	11.76	Methopt	QA
5517J OP	HYPROMELLOSE Eye drops 5 mg per mL (0.5%), 15 mL, 1	1	5	..	10.61	11.76	Methopt	QA
HYPROMELLOSE								
<u>Restricted benefit</u>								
For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements								
<u>Note</u>								
No applications for increased maximum quantities and/or repeats will be authorised.								
9213X	HYPROMELLOSE Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative), 1	1	11	..	10.61	11.76	^a In a Wink Moisturising	IQ
9214Y	HYPROMELLOSE Eye drops 5 mg per mL (0.5%), 15 mL, 1	1	11	^B 1.95	12.56	11.76	^a Genteal	AQ
				..	10.61	11.76	Methopt	QA
HYPROMELLOSE + CARBOMER-980								
<u>Restricted benefit</u>								
Severe dry eye syndrome, including Sjogren's syndrome								
5519L OP	hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g	1	5	..	10.61	11.76	^a HPMC PAA	IQ
8564R NP	hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g	1	5	^B 1.95	12.56	11.76	^a Genteal gel	AQ
				..	10.61	11.76	^a HPMC PAA	IQ
				^B 1.95	12.56	11.76	^a Genteal gel	AQ
HYPROMELLOSE + CARBOMER-980								
<u>Restricted benefit</u>								
For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements								
<u>Note</u>								
No applications for increased maximum quantities and/or repeats will be authorised.								
9215B	hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g	1	11	..	10.61	11.76	^a HPMC PAA	IQ
				^B 1.95	12.56	11.76	^a Genteal gel	AQ
PARAFFIN								
1750D NP	paraffin 1 g/g eye ointment, 2 x 3.5 g tubes	1	5	..	20.94	22.09	^a Ircal	PE
				^B 2.12	23.06	22.09	^a Poly Visc	IQ
							^a Refresh Night Time	AG

SENSORY ORGANS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
5522P OP	paraffin 1 g/g eye ointment, 2 x 3.5 g tubes	1	5	..	20.94	22.09	Poly Visc	IQ
				^B 2.12	23.06	22.09	^a Ircal	PE
1754H NP	paraffin 1 g/g eye ointment, 3.5 g	2	5	..	*21.58	22.73	^a Refresh Night Time	AG
				^B 2.54	*24.12	22.73	^a Poly Visc	IQ
5523Q OP	paraffin 1 g/g eye ointment, 3.5 g	2	5	..	*21.58	22.73	^a Duratears	AQ
				^B 2.54	*24.12	22.73	^a Poly Visc	IQ
				^B 2.54	*24.12	22.73	^a Duratears	AQ

PARAFFIN

Restricted benefit

For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

Note

No applications for increased maximum quantities and/or repeats will be authorised.

9218E	paraffin 1 g/g eye ointment, 2 x 3.5 g tubes	1	11	..	20.94	22.09	Poly Visc	IQ
				^B 2.12	23.06	22.09	^a Ircal	PE
9217D	paraffin 1 g/g eye ointment, 3.5 g	2	11	..	*21.58	22.73	^a Refresh Night Time	AG
				^B 2.54	*24.12	22.73	^a Poly Visc	IQ
				^B 2.54	*24.12	22.73	^a Duratears	AQ

PARAFFIN

Note

The in-use shelf life of VitA-POS is 6 months from the date of opening.

2167C OP	paraffin + retinyl palmitate 138 microgram/g (equivalent to 250 units/g vitamin A) eye ointment, 5 g	2	5	..	*21.58	22.73	VitA-POS	AE
2222Y NP	paraffin + retinyl palmitate 138 microgram/g (equivalent to 250 units/g vitamin A) eye ointment, 5 g	2	5	..	*21.58	22.73	VitA-POS	AE

PARAFFIN

Restricted benefit

For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

Note

The in-use shelf life of VitA-POS is 6 months from the date of opening.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

2202X	paraffin + retinyl palmitate 138 microgram/g (equivalent to 250 units/g vitamin A) eye ointment, 5 g	2	11	..	*21.58	22.73	VitA-POS	AE

POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

5524R OP	polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL	1	5	..	10.93	12.08	Systane	AQ
8676P NP	polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL	1	5	..	10.93	12.08	Systane	AQ

POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL

Restricted benefit

For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

Note

SENSORY ORGANS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
No applications for increased maximum quantities and/or repeats will be authorised.								
9219F	polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL	‡1	11	..	10.93	12.08	Systane	AQ
POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL								
<u>Authority required</u>								
Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops								
5532E OP	polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses	2	5	..	*34.42	35.57	Systane	AQ
POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL								
<u>Authority required (STREAMLINED)</u>								
1359								
Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops								
9170P NP	polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses	2	5	..	*34.42	35.57	Systane	AQ
POLYVINYL ALCOHOL								
<u>Restricted benefit</u>								
Severe dry eye syndrome, including Sjogren's syndrome								
2682E NP	polyvinyl alcohol 1.4% eye drops, 15 mL	‡1	5	..	10.61	11.76	^a PVA Tears	PE
5526W OP	polyvinyl alcohol 1.4% eye drops, 15 mL	‡1	5	^B 1.60	12.21	11.76	^a Liquifilm Tears	AG
				..	10.61	11.76	^a PVA Tears	PE
5527X OP	polyvinyl alcohol 1.4% eye drops, 15 mL	‡1	5	^B 1.60	12.21	11.76	^a Liquifilm Tears	AG
				..	10.61	11.76	Vistil	AE
8831T NP	polyvinyl alcohol 1.4% eye drops, 15 mL	‡1	5	..	10.61	11.76	Vistil	AE
5528Y OP	polyvinyl alcohol 3% eye drops, 15 mL	‡1	5	..	10.61	11.76	Vistil Forte	AE
8832W NP	polyvinyl alcohol 3% eye drops, 15 mL	‡1	5	..	10.61	11.76	Vistil Forte	AE
POLYVINYL ALCOHOL								
<u>Restricted benefit</u>								
For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements								
<u>Note</u>								
No applications for increased maximum quantities and/or repeats will be authorised.								
9220G	polyvinyl alcohol 1.4% eye drops, 15 mL	‡1	11	..	10.61	11.76	^a PVA Tears	PE
9221H	polyvinyl alcohol 1.4% eye drops, 15 mL	‡1	11	^B 1.60	12.21	11.76	^a Liquifilm Tears	AG
				..	10.61	11.76	Vistil	AE
9223K	polyvinyl alcohol 3% eye drops, 15 mL	‡1	11	..	10.61	11.76	Vistil Forte	AE
SODIUM HYALURONATE								
<u>Authority required (STREAMLINED)</u>								
4105								
Severe dry eye syndrome								
Clinical criteria:								
Patient must be sensitive to preservatives in multi-dose eye drops.								
<u>Note</u>								
The in-use shelf life of Hylo-Fresh and Hylo-Forte is 6 months from the date of opening.								
2181T NP	sodium hyaluronate 0.1% (1 mg/mL) eye drops, 10 mL	‡1	5	..	33.96	35.11	Hylo-Fresh	AE
2253N NP	sodium hyaluronate 0.2% (2 mg/mL) eye drops, 10 mL	‡1	5	..	33.96	35.11	Hylo-Forte	AE

SENSORY ORGANS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
SODIUM HYALURONATE								
<u>Authority required</u>								
Severe dry eye syndrome								
<u>Clinical criteria:</u>								
Patient must be sensitive to preservatives in multi-dose eye drops.								
<u>Note</u>								
The in-use shelf life of Hylo-Fresh and Hylo-Forte is 6 months from the date of opening.								
2184Y OP	sodium hyaluronate 0.1% (1 mg/mL) eye drops, 10 mL	‡1	5	..	33.96	35.11	Hylo-Fresh	AE
2171G OP	sodium hyaluronate 0.2% (2 mg/mL) eye drops, 10 mL	‡1	5	..	33.96	35.11	Hylo-Forte	AE
SOY LECITHIN + TOCOPHEROLS + VITAMIN A								
<u>Authority required</u>								
Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops								
5545W OP	soy lecithin 1% (10 mg/mL) + tocopherols 0.002% (20 microgram/mL) + vitamin A palmitate 0.025% (250 microgram/mL) eye spray, 100 actuations	2	5	..	*36.40	37.55	tearsagain	RB
SOY LECITHIN + TOCOPHEROLS + VITAMIN A								
<u>Authority required (STREAMLINED)</u>								
1359								
Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops								
9448G NP	soy lecithin 1% (10 mg/mL) + tocopherols 0.002% (20 microgram/mL) + vitamin A palmitate 0.025% (250 microgram/mL) eye spray, 100 actuations	2	5	..	*36.40	37.55	tearsagain	RB

OTOLOGICALS

ANTIINFECTIVES

Antiinfectives

CHLORAMPHENICOL								
1172Q NP	chloramphenicol 0.5% ear drops, 5 mL	‡1	2	..	11.39	12.54	Chloromycetin	PF
CIPROFLOXACIN								
<u>Authority required</u>								
Treatment of chronic suppurative otitis media in an Aboriginal or a Torres Strait Islander person aged 1 month or older								
<u>Authority required</u>								
Treatment of chronic suppurative otitis media in a patient less than 18 years of age with perforation of the tympanic membrane								
<u>Authority required</u>								
Treatment of chronic suppurative otitis media in a patient less than 18 years of age with a grommet in situ								
2480M NP	ciprofloxacin 0.3% ear drops, 5 mL	‡1	1	..	19.62	20.77	Ciloxan	AQ

CORTICOSTEROIDS AND ANTIINFECTIVES IN COMBINATION

Corticosteroids and antiinfectives in combination

DEXAMETHASONE + FRAMYCETIN SULFATE + GRAMICIDIN								
2781J NP	dexamethasone 0.05% (500 microgram/mL) + framycetin sulfate 0.5% (5 mg/mL) + gramicidin 0.005% (50 microgram/mL) ear drops, 8 mL	‡1	2	..	10.28	11.43	^a Otodex	AV
				^b 1.91	12.19	11.43	^a Sofradex	SW
TRIAMCINOLONE + NEOMYCIN SULFATE + GRAMICIDIN + NYSTATIN								
2974M NP	triamcinolone acetate 0.1% + neomycin sulfate 0.25% + gramicidin 0.025% + nystatin 100 000 international units/g ointment, 5 g	‡1	2	..	8.52	9.67	^a Otocomb Otic	FM

SENSORY ORGANS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
2971J	triamcinolone acetonide 0.1% +	‡1	2	^B 1.95	10.47	9.67	^a Kenacomb Otic	QA
NP	neomycin sulfate 0.25% + gramicidin 0.025% + nystatin 100 000 international units/mL ear drops, 7.5 mL			..	11.43	12.58	^a Otocomb Otic	FM
				^B 1.95	13.38	12.58	^a Kenacomb Otic	QA

OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS

ANTIINFECTIVES

Antiinfectives

FRAMYCETIN SULFATE

1440T	framycetin sulfate 0.5% (5 mg/mL)	‡1	2	..	11.08	12.23	Soframycin	SW
NP, MW	eye/ear drops, 8 mL							
5557L	framycetin sulfate 0.5% (5 mg/mL)	‡1	2	..	11.08	12.23	Soframycin	SW
OP	eye/ear drops, 8 mL							

VARIOUS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

VARIOUS

ALLERGENS

ALLERGENS

Allergen extracts

BEE VENOM								
2886X	bee venom 550 microgram injection [1 x 550 microgram vial] (&) inert substance diluent [4 vials], 1 pack	1	..	..	238.72	37.70	Albey Bee Venom	HL
PAPER WASP VENOM								
Note								
Paper wasp venom is not European wasp venom.								
2918N	paper wasp venom 550 microgram injection [1 x 550 microgram vial] (&) inert substance diluent [4 vials], 1 pack	1	..	..	238.72	37.70	Albey Paper Wasp Venom	HL
VESPULA SPP VENOM								
2883R	vespula spp venom 550 microgram injection [1 x 550 microgram vial] (&) inert substance diluent [4 vials], 1 pack	1	..	..	238.72	37.70	Albey Yellow Jacket Venom	HL

ALL OTHER THERAPEUTIC PRODUCTS

ALL OTHER THERAPEUTIC PRODUCTS

Antidotes

NALOXONE								
2192J NP	naloxone hydrochloride 400 microgram/mL injection, 1 x 1 mL syringe	5	..	..	*105.16	37.70	Naloxone minijet	UC
2196N DP	naloxone hydrochloride 400 microgram/mL injection, 1 x 1 mL syringe	5	..	..	*105.16	37.70	Naloxone minijet	UC

*Drugs for treatment of hyperkalemia and hyperphosphatemia***LANTHANUM****Authority required (STREAMLINED)**

4827

Hyperphosphataemia

Treatment Phase: Maintenance following initiation and stabilisation

Clinical criteria:

The condition must not be adequately controlled by calcium,

AND

Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR

The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy,

AND

The treatment must not be used in combination with any other phosphate binding agents.

Treatment criteria:

Patient must be undergoing dialysis for chronic kidney disease.

Note**Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

9405B NP	LANTHANUM Tablet, chewable, 1000 mg (as carbonate hydrate), 90	1	5	..	504.37	37.70	Fosrenol	ZI
9403X NP	LANTHANUM Tablet, chewable, 500 mg (as carbonate hydrate), 90	1	5	..	306.22	37.70	Fosrenol	ZI

VARIOUS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
9404Y NP	LANTHANUM Tablet, chewable, 750 mg (as carbonate hydrate), 90	1	5	..	449.77	37.70	Fosrenol	ZI

SEVELAMER

Authority required (STREAMLINED)

4827

Hyperphosphataemia

Treatment Phase: Maintenance following initiation and stabilisation

Clinical criteria:

The condition must not be adequately controlled by calcium,

AND

Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR

The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy,

AND

The treatment must not be used in combination with any other phosphate binding agents.

Treatment criteria:

Patient must be undergoing dialysis for chronic kidney disease.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2142R NP	sevelamer hydrochloride 800 mg tablet, 180	1	5	..	358.07	37.70	Renagel	GZ

SUCROFERRIC OXYHYDROXIDE

Authority required (STREAMLINED)

4827

Hyperphosphataemia

Treatment Phase: Maintenance following initiation and stabilisation

Clinical criteria:

The condition must not be adequately controlled by calcium,

AND

Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR

The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy,

AND

The treatment must not be used in combination with any other phosphate binding agents.

Treatment criteria:

Patient must be undergoing dialysis for chronic kidney disease.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

10250L NP	iron (as sucroferric oxyhydroxide) 500 mg tablet: chewable, 90	1	5	..	429.82	37.70	Velphoro	FN

Detoxifying agents for antineoplastic treatment

FOLINIC ACID

8969C	folinic acid 1 g/100 mL injection, 1 x 100 mL vial	1	1	..	54.77	37.70	Calcium Folate Ebewe	SZ
9041W	folinic acid 300 mg/30 mL injection, 1 x 30 mL vial	4	1	..	*62.76	37.70	^a Calcium Folate Ebewe	SZ
							^a Leucovorin Calcium (Hospira Pty Limited)	HH

FOLINIC ACID

Note

For item codes 8812T and 1704Q, pharmaceutical benefits that have the form injection equivalent to 100 mg folinic acid in 10 mL are equivalent for the purposes of substitution.

VARIOUS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
8812T	folinic acid 100 mg/10 mL injection, 1 x 10 mL vial	10	1	..	*54.76	37.70	^a Calcium Folate Ebewe	SZ
1704Q	folinic acid 100 mg/10 mL injection, 10 x 10 mL ampoules	1	1	..	54.81	37.70	^a Leucovorin Calcium (Pfizer Australia Pty Ltd)	PF
FOLINIC ACID								
<u>Restricted benefit</u>								
Antidote to folic acid antagonists								
2308L	folinic acid 15 mg tablet, 10	1	..	..	96.65	37.70	Leucovorin Calcium (Hospira Pty Limited)	HH
FOLINIC ACID								
<u>Note</u>								
For item codes 8740B and 1610R, pharmaceutical benefits that have the form injection equivalent to 50 mg folinic acid in 5 mL are equivalent for the purposes of substitution.								
8740B	folinic acid 50 mg/5 mL injection, 1 x 5 mL vial	10	2	..	*58.56	37.70	^a Leucovorin Calcium (Hospira Pty Limited)	HH
1610R	folinic acid 50 mg/5 mL injection, 10 x 5 mL ampoules	1	2	..	58.56	37.70	^a Leucovorin Calcium (Pfizer Australia Pty Ltd)	PF
MESNA								
<u>Restricted benefit</u>								
Adjunctive therapy for use with ifosfamide or high dose cyclophosphamide								
8079F	mesna 1 g/10 mL injection, 15 x 10 mL ampoules	1	5	..	224.15	37.70	Uromitexan	BX
8078E	mesna 400 mg/4 mL injection, 15 x 4 mL ampoules	1	5	..	103.62	37.70	Uromitexan	BX

Drugs for treatment of hypercalcemia**PHOSPHORUS****Authority required (STREAMLINED)****1099**

Familial hypophosphataemia

Authority required (STREAMLINED)**1157**

Hypercalcaemia

Authority required (STREAMLINED)**1167**

Hypophosphataemic rickets

Authority required (STREAMLINED)**1467**

Vitamin D-resistant rickets

2946C NP	phosphorus 500 mg tablet: effervescent, 100	1	5	..	81.97	37.70	Phosphate Sandoz	NV

Other therapeutic products**POLYLACTIC ACID****Authority required**

Initial PBS-subsidised treatment, for facial administration only, of severe facial lipoatrophy caused by therapy for HIV infection.

Accreditation following completion of injection administration training with Sanofi-Aventis is required to prescribe poly-L-lactic acid under the PBS. Patients must be referred from the HIV physician to the accredited injector

Note

Authority applications to prescribe poly-L-lactic acid may be made by telephone to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note

No applications for increased maximum quantities and/or repeats will be authorised.

9475Q	polylactic acid 150 mg injection, 1 x 150 mg vial	2	4	..	*446.80	37.70	Sculptra	GA

POLYLACTIC ACID**Authority required**

VARIOUS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Maintenance PBS-subsidised treatment, for facial administration only, of severe facial lipoatrophy caused by therapy for HIV infection.							
	Accreditation following completion of injection administration training with Sanofi-Aventis is required to prescribe poly-L-lactic acid under the PBS. Patients must be referred from the HIV physician to the accredited injector							
	Note							
	Authority applications to prescribe poly-L-lactic acid may be made by telephone to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).							
	Note							
	No applications for increased maximum quantities and/or repeats will be authorised.							
	Maintenance treatment is limited to one re-treatment (maximum 2 vials) every 2 years.							
9476R	polylactic acid 150 mg injection, 1 x 150 mg vial	2	..	..	*446.80	37.70	Sculptra	GA

DIAGNOSTIC AGENTS

URINE TESTS

GLUCOSE AND KETONE INDICATOR URINE

3106L NP	glucose and ketone indicator urine strip: diagnostic, 50 diagnostic strips	2	2	..	*17.64	18.79	Keto-Diabur- Test 5000	RD
3107M NP	glucose and ketone indicator urine strip: diagnostic, 50 diagnostic strips	2	2	..	*17.76	18.91	Keto-Diastix	BN

GLUCOSE AND KETONE INDICATOR URINE

Restricted benefit

For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

Note

No applications for increased maximum quantities and/or repeats will be authorised.

9254C	glucose and ketone indicator urine strip: diagnostic, 50 diagnostic strips	2	4	..	*17.64	18.79	Keto-Diabur- Test 5000	RD
9255D	glucose and ketone indicator urine strip: diagnostic, 50 diagnostic strips	2	4	..	*17.76	18.91	Keto-Diastix	BN

GLUCOSE INDICATOR URINE

3104J NP	glucose indicator urine strip: diagnostic, 50 diagnostic strips	2	2	..	*20.16	21.31	Diastix	BN

GLUCOSE INDICATOR URINE

Restricted benefit

For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

Note

No applications for increased maximum quantities and/or repeats will be authorised.

9253B	glucose indicator urine strip: diagnostic, 50 diagnostic strips	2	4	..	*20.16	21.31	Diastix	BN

OTHER DIAGNOSTIC AGENTS

Tests for diabetes

GLUCOSE INDICATOR BLOOD

Restricted benefit

Blood glucose monitoring

Clinical criteria:

Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

10099M	glucose indicator blood strip: diagnostic, 100	1	11	..	53.50	37.70	GoodLife	JN
10141R	glucose indicator blood strip: diagnostic, 100	1	11	..	53.50	37.70	EasyMate II	WI

VARIOUS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
10164Y	glucose indicator blood strip: diagnostic, 100	‡1	11	..	53.50	37.70	Contour next	IK
10222B	glucose indicator blood strip: diagnostic, 100	‡1	11	..	53.50	37.70	Dario	UH
1518X	glucose indicator blood strip: diagnostic, 100	‡1	11	..	53.50	37.70	Contour	IK
1520B	glucose indicator blood strip: diagnostic, 100	‡1	11	..	53.50	37.70	BGStar	SW
2568E	glucose indicator blood strip: diagnostic, 100	‡1	11	..	53.50	37.70	TRUEresult	NX
2571H	glucose indicator blood strip: diagnostic, 100	‡1	11	..	53.50	37.70	TRUEbalance	NX
2602Y	glucose indicator blood strip: diagnostic, 100	‡1	11	..	53.50	37.70	TRUEtrack	NX
3412N	glucose indicator blood strip: diagnostic, 100	‡1	11	..	53.50	37.70	Accu-Chek Advantage/Sensor Comfort	RD
9257F	glucose indicator blood strip: diagnostic, 100	‡1	11	..	53.50	37.70	Accu-Chek Performa	RD
9269W	glucose indicator blood strip: diagnostic, 100	‡1	11	..	53.50	37.70	FreeStyle Lite	MS
9270X	glucose indicator blood strip: diagnostic, 100	‡1	11	..	53.50	37.70	FreeStyle Optium	MS
9273C	glucose indicator blood strip: diagnostic, 100	‡1	11	..	53.50	37.70	Accu-Chek Active	RD
10139P	glucose indicator blood strip: diagnostic, 50	2	11	..	*53.52	37.70	EasyMate II	WI
10215P	glucose indicator blood strip: diagnostic, 50	2	11	..	*53.52	37.70	Healthpro	IF
10217R	glucose indicator blood strip: diagnostic, 50	2	11	..	*53.52	37.70	GluNEO	IF
2697Y	glucose indicator blood strip: diagnostic, 50	2	11	..	*53.52	37.70	OneTouch Select	JJ
3407H	glucose indicator blood strip: diagnostic, 50	2	11	..	*53.52	37.70	CareSens N	PB
3442E	glucose indicator blood strip: diagnostic, 50	2	11	..	*53.52	37.70	OneTouch Verio	JJ
5053Y	glucose indicator blood strip: diagnostic, 50	2	11	..	*53.52	37.70	Accu-Chek Aviva	RD
9263M	glucose indicator blood strip: diagnostic, 50	2	11	..	*53.52	37.70	GlucoDr	OZ
9267R	glucose indicator blood strip: diagnostic, 50	2	11	..	*53.52	37.70	Optium Omega	MS
9274D	glucose indicator blood strip: diagnostic, 50	2	11	..	*53.52	37.70	Accu-Chek Go	RD
9276F	glucose indicator blood strip: diagnostic, 50	2	11	..	*53.52	37.70	Betachek	NA
9277G	glucose indicator blood strip: diagnostic, 50	2	11	..	*53.52	37.70	Betachek G5	NA
9278H	glucose indicator blood strip: diagnostic, 50	2	11	..	*53.52	37.70	CareSens	PB
9279J	glucose indicator blood strip: diagnostic, 50	2	11	..	*46.24	37.70	Glucoflex-R	NA
9281L	glucose indicator blood strip: diagnostic, 50	2	11	..	*53.52	37.70	SensoCard	PX
9297H	glucose indicator blood strip: diagnostic, 50	2	11	..	*53.52	37.70	Bionime Rightest	QB
9472M	glucose indicator blood strip: diagnostic, 50	2	11	..	*53.52	37.70	MyGlucoHealth	EH
9486G	glucose indicator blood strip: diagnostic, 50	2	11	..	*53.52	37.70	Lifeline Attest	OI
9275E	glucose indicator blood strip:	2	11	..	*53.52	37.70	Accu-Chek Integra	RD

VARIOUS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	diagnostic, 51 diagnostic strips							
GLUCOSE INDICATOR BLOOD								
10101P NP	glucose indicator blood strip: diagnostic, 100	‡1	5	..	53.50	37.70	GoodLife	JN
10145Y NP	glucose indicator blood strip: diagnostic, 100	‡1	5	..	53.50	37.70	EasyMate II	WI
10153J NP	glucose indicator blood strip: diagnostic, 100	‡1	5	..	53.50	37.70	Contour next	IK
10221Y NP	glucose indicator blood strip: diagnostic, 100	‡1	5	..	53.50	37.70	Dario	UH
1503D NP	glucose indicator blood strip: diagnostic, 100	‡1	5	..	53.50	37.70	Contour	IK
1519Y NP	glucose indicator blood strip: diagnostic, 100	‡1	5	..	53.50	37.70	BGStar	SW
2562W NP	glucose indicator blood strip: diagnostic, 100	‡1	5	..	53.50	37.70	TRUEbalance	NX
2575M NP	glucose indicator blood strip: diagnostic, 100	‡1	5	..	53.50	37.70	TRUEtrack	NX
2624D NP	glucose indicator blood strip: diagnostic, 100	‡1	5	..	53.50	37.70	TRUEresult	NX
2979T NP	glucose indicator blood strip: diagnostic, 100	‡1	5	..	53.50	37.70	Accu-Chek Performa	RD
3411M NP	glucose indicator blood strip: diagnostic, 100	‡1	5	..	53.50	37.70	Accu-Chek Advantage/Sensor Comfort	RD
8190C NP	glucose indicator blood strip: diagnostic, 100	‡1	5	..	53.50	37.70	Accu-Chek Active	RD
8522M NP	glucose indicator blood strip: diagnostic, 100	‡1	5	..	53.50	37.70	FreeStyle Optium	MS
9154T NP	glucose indicator blood strip: diagnostic, 100	‡1	5	..	53.50	37.70	FreeStyle Lite	MS
10147C NP	glucose indicator blood strip: diagnostic, 50	2	5	..	*53.52	37.70	EasyMate II	WI
10216Q NP	glucose indicator blood strip: diagnostic, 50	2	5	..	*53.52	37.70	Healthpro	IF
10223C NP	glucose indicator blood strip: diagnostic, 50	2	5	..	*53.52	37.70	GlucEO	IF
2263D NP	glucose indicator blood strip: diagnostic, 50	2	5	..	*53.52	37.70	Optium Omega	MS
2673Q NP	glucose indicator blood strip: diagnostic, 50	2	5	..	*53.52	37.70	OneTouch Select	JJ
2860M NP	glucose indicator blood strip: diagnostic, 50	2	5	..	*53.52	37.70	Betachek G5	NA
2890D NP	glucose indicator blood strip: diagnostic, 50	2	5	..	*53.52	37.70	Betachek	NA
2914J NP	glucose indicator blood strip: diagnostic, 50	2	5	..	*46.24	37.70	Gluciflex-R	NA
3406G NP	glucose indicator blood strip: diagnostic, 50	2	5	..	*53.52	37.70	CareSens N	PB
3441D NP	glucose indicator blood strip: diagnostic, 50	2	5	..	*53.52	37.70	OneTouch Verio	JJ
5043K NP	glucose indicator blood strip: diagnostic, 50	2	5	..	*53.52	37.70	Accu-Chek Aviva	RD
8739Y NP	glucose indicator blood strip: diagnostic, 50	2	5	..	*53.52	37.70	Accu-Chek Go	RD
8749L NP	glucose indicator blood strip: diagnostic, 50	2	5	..	*53.52	37.70	GlucOdr	OZ
8759B NP	glucose indicator blood strip: diagnostic, 50	2	5	..	*53.52	37.70	CareSens	PB
8795X NP	glucose indicator blood strip: diagnostic, 50	2	5	..	*53.52	37.70	SensoCard	PX
9298J NP	glucose indicator blood strip: diagnostic, 50	2	5	..	*53.52	37.70	Bionime Rightest	QB
9471L NP	glucose indicator blood strip: diagnostic, 50	2	5	..	*53.52	37.70	MyGlucOHealth	EH
9485F NP	glucose indicator blood strip: diagnostic, 50	2	5	..	*53.52	37.70	Lifeline Attest	OI
8806L NP	glucose indicator blood strip: diagnostic, 51 diagnostic strips	2	5	..	*53.52	37.70	Accu-Chek Integra	RD

VARIOUS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
GLUCOSE INDICATOR BLOOD								
<u>Restricted benefit</u>								
For use in patients on insulin therapy								
9300L NP	glucose indicator blood strip: diagnostic, 100	‡1	5	..	53.50	37.70	Accu-Chek Mobile	RD
GLUCOSE INDICATOR BLOOD								
<u>Restricted benefit</u>								
For use in patients on insulin therapy who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements								
<u>Note</u>								
No applications for increased maximum quantities and/or repeats will be authorised.								
9301M	glucose indicator blood strip: diagnostic, 100	‡1	11	..	53.50	37.70	Accu-Chek Mobile	RD

GENERAL NUTRIENTS

OTHER NUTRIENTS

TRIGLYCERIDES LONG CHAIN

Restricted benefit

Ketogenic diet

Clinical criteria:

Patient must have intractable seizures requiring treatment with a ketogenic diet; OR

Patient must have a glucose transport protein defect; OR

Patient must have pyruvate dehydrogenase deficiency.

Carbzero should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

Note

Carbzero is not nutritionally complete and is not intended for use as a sole source of nutrition.

10037G NP	triglycerides long chain oral liquid, 18 x 250 mL cartons	2	5	..	*300.16	37.70	carbzero	VF

TRIGLYCERIDES MEDIUM CHAIN

Authority required

Chylous ascites

Authority required

Chyllothorax

Authority required

Fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders

Authority required

Hyperlipoproteinaemia type 1

Authority required

Intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect, requiring a ketogenic diet

Authority required

Long chain fatty acid oxidation disorders

Note

No applications for increased maximum quantities and/or repeats will be authorised.

3128P NP	triglycerides medium chain oil: oral, 500 mL	2	5	..	*52.72	37.70	MCT Oil	SB
9327X NP	triglycerides medium chain oral liquid, 1 x 250 mL bottle	8	5	..	*214.76	37.70	Liquigen	SB

TRIGLYCERIDES MEDIUM CHAIN

Authority required

Ketogenic diet

Clinical criteria:

Patient must have intractable seizures requiring treatment with a ketogenic diet; OR

Patient must have a glucose transport protein defect; OR

Patient must have pyruvate dehydrogenase deficiency.

VARIOUS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	<u>Authority required</u>						
	Dietary management of conditions requiring a source of medium chain triglycerides						
	<u>Clinical criteria:</u>						
	Patient must have chylous ascites; OR						
	Patient must have chylothorax; OR						
	Patient must have hyperlipoproteinaemia type 1; OR						
	Patient must have long chain fatty acid oxidation disorders; OR						
	Patient must have fat malabsorption due to liver disease; OR						
	Patient must have fat malabsorption due to short gut syndrome; OR						
	Patient must have fat malabsorption due to cystic fibrosis; OR						
	Patient must have fat malabsorption due to gastrointestinal disorders.						
	<u>Note</u>						
	No increase in the maximum quantity or number of units may be authorised.						
	<u>Note</u>						
	No increase in the maximum number of repeats may be authorised.						
10049X NP	triglycerides medium chain oral liquid, 18 x 250 mL cartons	2	5	..	*383.86	37.70	betaquik VF

Fat/carbohydrates/proteins/minerals/vitamins, combinations

AMINO ACID SYNTHETIC FORMULA

Authority required

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

Clinical criteria:

The condition must not be isolated infant colic or reflux,

AND

Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

Clinical criteria:

The condition must not be isolated infant colic or reflux.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

Clinical criteria:

VARIOUS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	The condition must not be isolated infant colic or reflux.							
	Population criteria:							
	Patient must be older than 24 months of age.							
	Treatment criteria:							
	Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.							
	The name of the specialist and the date of birth of the patient must be included in the authority application.							
	Authority required							
	Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein							
	Treatment Phase: Initial treatment for up to 6 months							
	Clinical criteria:							
	Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).							
	Population criteria:							
	Patient must be up to the age of 24 months.							
	Treatment criteria:							
	Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.							
	The name of the specialist and the date of birth of the patient must be included in the authority application.							
	Note							
	No increase in the maximum quantity or number of units may be authorised.							
	Note							
	No increase in the maximum number of repeats may be authorised.							
1180D NP	amino acid synthetic formula oral liquid: powder for, 400 g	8	5	..	*361.48	37.70	Neocate Advance Vanilla	SB
8574G NP	amino acid synthetic formula oral liquid: powder for, 400 g	8	5	..	*361.48	37.70	EleCare	AB
8754R NP	amino acid synthetic formula oral liquid: powder for, 400 g	8	5	..	*361.48	37.70	Neocate Advance	SB

AMINO ACID SYNTHETIC FORMULA

Authority required

Cows' milk anaphylaxis

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must not be isolated infant colic or reflux,

AND

Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

Patient must be up to the age of 24 months.

VARIOUS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must not be isolated infant colic or reflux,

AND

Patient must have had failure to thrive prior to commencement with initial treatment.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must not be isolated infant colic or reflux.

Population criteria:

Patient must be older than 24 months of age.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe intestinal malabsorption including short bowel syndrome

Clinical criteria:

Patient must have failed to respond to protein hydrolysate formulae; OR

Patient must have been receiving parenteral nutrition.

Note

VARIOUS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.								
1192R NP	amino acid synthetic formula oral liquid: powder for, 400 g	8	5	..	*361.48	37.70	Neocate Advance Vanilla	SB
8575H NP	amino acid synthetic formula oral liquid: powder for, 400 g	8	5	..	*361.48	37.70	EleCare	AB
8755T NP	amino acid synthetic formula oral liquid: powder for, 400 g	8	5	..	*361.48	37.70	Neocate Advance	SB

AMINO ACID SYNTHETIC FORMULA

Authority required

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

Clinical criteria:

Patient must require an amino acid based formula as a component of a dietary elimination program.

Population criteria:

Patient must be 18 years of age or less.

Treatment criteria:

Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

- (i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and
- (ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and
- (iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

Authority required

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have responded to an initial course of PBS-subsidised treatment.

Population criteria:

Patient must be 18 years of age or less.

Treatment criteria:

Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

Note

Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.

1521C NP	amino acid synthetic formula oral liquid: powder for, 400 g	12	5	..	*532.00	37.70	Neocate Advance Vanilla	SB
2250K NP	amino acid synthetic formula oral liquid: powder for, 400 g	12	5	..	*532.00	37.70	EleCare	AB

AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS

Authority required

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

[illegible]

VARIOUS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Note No increase in the maximum number of repeats may be authorised.							
2246F NP	amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids oral liquid: powder for, 400 g	8	5	..	*368.20	37.70	Neocate LCP	SB
9339M NP	amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids oral liquid: powder for, 400 g	8	5	..	*368.20	37.70	EleCare LCP	AB

AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS

Authority required

Cows' milk anaphylaxis

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must not be isolated infant colic or reflux,

AND

Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must not be isolated infant colic or reflux,

AND

Patient must have had failure to thrive prior to commencement with initial treatment.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

VARIOUS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must not be isolated infant colic or reflux.

Population criteria:

Patient must be older than 24 months of age.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe intestinal malabsorption including short bowel syndrome

Clinical criteria:

Patient must have failed to respond to protein hydrolysate formulae; OR

Patient must have been receiving parenteral nutrition.

Note

Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

2560R NP	amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids oral liquid: powder for, 400 g	8	5	..	*368.20	37.70	Neocate LCP	SB
9340N NP	amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids oral liquid: powder for, 400 g	8	5	..	*368.20	37.70	EleCare LCP	AB

AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

Authority required

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

Clinical criteria:

Patient must require an amino acid based formula as a component of a dietary elimination program.

Population criteria:

Patient must be 18 years of age or less.

Treatment criteria:

Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Treatment with oral steroids should not be commenced during the period of initial treatment.

VARIOUS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

Eosinophilic oesophagitis is demonstrated by the following criteria:

- (i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and
- (ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and
- (iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

Authority required

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have responded to an initial course of PBS-subsidised treatment.

Population criteria:

Patient must be 18 years of age or less.

Treatment criteria:

Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

Note

Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.

1545H NP	amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides oral liquid: powder for, 400 g	12	5	..	*542.56	37.70	Neocate Gold	SB

AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

Authority required

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must not be isolated infant colic or reflux,

AND

Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

Clinical criteria:

VARIOUS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	The condition must not be isolated infant colic or reflux, AND Patient must have had failure to thrive prior to commencement with initial treatment. Population criteria: Patient must be up to the age of 24 months. Treatment criteria: Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists. The name of the specialist and the date of birth of the patient must be included in the authority application. <u>Authority required</u> Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae Treatment Phase: Continuing treatment Clinical criteria: The condition must not be isolated infant colic or reflux. Population criteria: Patient must be older than 24 months of age. Treatment criteria: Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months. The name of the specialist and the date of birth of the patient must be included in the authority application. <u>Authority required</u> Cows' milk anaphylaxis Population criteria: Patient must be up to the age of 24 months. Treatment criteria: Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist. Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction. The name of the specialist and the date of birth of the patient must be included in the authority application. <u>Authority required</u> Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein Treatment Phase: Continuing treatment Clinical criteria: Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment. Population criteria: Patient must be up to the age of 24 months. Treatment criteria: Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist. The name of the specialist and the date of birth of the patient must be included in the authority application. <u>Note</u> Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.						
2900P	amino acid synthetic formula	8	5	..	*368.20	37.70	Alfamino NT

VARIOUS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

NP

supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides oral liquid: powder for, 400 g

AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

Authority required

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

Clinical criteria:

The condition must not be isolated infant colic or reflux,

AND

Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

Clinical criteria:

The condition must not be isolated infant colic or reflux.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

Clinical criteria:

The condition must not be isolated infant colic or reflux.

Population criteria:

Patient must be older than 24 months of age.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

Clinical criteria:

Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

Population criteria:

VARIOUS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

2928D NP	amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides oral liquid: powder for, 400 g	8	5	..	*368.20	37.70	Alfamino	NT
5466Q NP	amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides oral liquid: powder for, 400 g	8	5	..	*368.20	37.70	Neocate Gold	SB

AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

Authority required

Cows' milk anaphylaxis

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must not be isolated infant colic or reflux,

AND

Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

Clinical criteria:

VARIOUS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	The condition must not be isolated infant colic or reflux, AND Patient must have had failure to thrive prior to commencement with initial treatment. Population criteria: Patient must be up to the age of 24 months. Treatment criteria: Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists. The name of the specialist and the date of birth of the patient must be included in the authority application. Authority required Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae Treatment Phase: Continuing treatment Clinical criteria: The condition must not be isolated infant colic or reflux. Population criteria: Patient must be older than 24 months of age. Treatment criteria: Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months. The name of the specialist and the date of birth of the patient must be included in the authority application. Authority required Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein Treatment Phase: Continuing treatment Clinical criteria: Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment. Population criteria: Patient must be up to the age of 24 months. Treatment criteria: Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist. The name of the specialist and the date of birth of the patient must be included in the authority application. Authority required Severe intestinal malabsorption including short bowel syndrome Clinical criteria: Patient must have failed to respond to protein hydrolysate formulae; OR Patient must have been receiving parenteral nutrition. Note Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.						
5467R NP	amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides oral liquid: powder for, 400 g	8	5	..	*368.20	37.70	Neocate Gold SB

PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES**Authority required**

Cows' milk protein enteropathy and intolerance to soy protein

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	Treatment Phase: Initial treatment Clinical criteria: The condition must not be isolated infant colic or reflux, AND Patient must have failed to respond to a strict soy-based cows' milk protein free diet. Population criteria: Patient must be up to the age of 24 months. Treatment criteria: Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist. The date of birth of the patient must be included in the authority application. Authority required Cows' milk protein enteropathy and intolerance to soy protein Treatment Phase: Continuing treatment Clinical criteria: The condition must not be isolated infant colic or reflux, AND Patient must have demonstrated a clinical improvement with the protein hydrolysate formula with medium chain triglycerides. Population criteria: Patient must be up to the age of 24 months. Treatment criteria: Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist. The date of birth of the patient must be included in the authority application. Authority required Cows' milk protein enteropathy and intolerance to soy protein Clinical criteria: The condition must not be isolated infant colic or reflux, AND Patient must have failed to respond to a strict soy-based cows' milk protein free diet. Population criteria: Patient must be older than 24 months of age. Treatment criteria: Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist. The name of the specialist and the date of birth of the patient must be included in the authority application. Authority required Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein Treatment Phase: Initial treatment for up to 6 months Population criteria: Patient must be up to the age of 24 months. Treatment criteria: Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist. The name of the specialist and the date of birth of the patient must be included in the authority application. Authority required						

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein						
	Treatment Phase: Continuing treatment						
	Population criteria:						
	Patient must be up to the age of 24 months.						
	Treatment criteria:						
	Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.						
	The name of the specialist and the date of birth of the patient must be included in the authority application.						
	<u>Authority required</u>						
	Biliary atresia						
	<u>Authority required</u>						
	Chronic liver failure with fat malabsorption						
	<u>Authority required</u>						
	Chylous ascites						
	<u>Authority required</u>						
	Cystic fibrosis						
	<u>Authority required</u>						
	Enterokinase deficiency						
	<u>Authority required</u>						
	Proven fat malabsorption						
	<u>Authority required</u>						
	Severe diarrhoea of greater than 2 weeks duration						
	Population criteria:						
	Patient must be aged less than 4 months.						
	The date of birth of the patient must be included in the authority application.						
	<u>Authority required</u>						
	Severe intestinal malabsorption including short bowel syndrome						
	<u>Authority required</u>						
	Chylothorax						
	<u>Note</u>						
	No increase in the maximum quantity or number of units may be authorised.						
	<u>Note</u>						
	No increase in the maximum number of repeats may be authorised.						
2676W NP	protein hydrolysate formula with medium chain triglycerides oral liquid: powder for, 400 g	8	5	..	*172.28	37.70	Alfaré NT
	PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES						
	<u>Authority required</u>						
	Cows' milk protein enteropathy and intolerance to soy protein						
	Treatment Phase: Initial treatment						
	Clinical criteria:						
	The condition must not be isolated infant colic or reflux,						
	AND						
	Patient must have failed to respond to a strict soy-based cows' milk protein free diet.						
	Population criteria:						
	Patient must be up to the age of 24 months.						
	Treatment criteria:						
	Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.						
	The date of birth of the patient must be included in the authority application.						

VARIOUS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

Authority required

Cows' milk protein enteropathy and intolerance to soy protein

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must not be isolated infant colic or reflux,

AND

Patient must have demonstrated a clinical improvement with the protein hydrolysate formula with medium chain triglycerides.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

The date of birth of the patient must be included in the authority application.

Authority required

Cows' milk protein enteropathy and intolerance to soy protein

Clinical criteria:

The condition must not be isolated infant colic or reflux,

AND

Patient must have failed to respond to a strict soy-based cows' milk protein free diet.

Population criteria:

Patient must be older than 24 months of age.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Biliary atresia

Authority required

VARIOUS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Chronic liver failure with fat malabsorption							
	<u>Authority required</u>							
	Chylous ascites							
	<u>Authority required</u>							
	Cystic fibrosis							
	<u>Authority required</u>							
	Enterokinase deficiency							
	<u>Authority required</u>							
	Proven fat malabsorption							
	<u>Authority required</u>							
	Severe diarrhoea of greater than 2 weeks duration							
	Population criteria:							
	Patient must be aged less than 4 months.							
	The date of birth of the patient must be included in the authority application.							
	<u>Authority required</u>							
	Severe intestinal malabsorption including short bowel syndrome							
	<u>Note</u>							
	No increase in the maximum quantity or number of units may be authorised.							
	<u>Note</u>							
	No increase in the maximum number of repeats may be authorised.							
8259Q NP	protein hydrolysate formula with medium chain triglycerides oral liquid: powder for, 450 g	8	5	..	*110.20	37.70	Karicare Aptamil Pepti-Junior Gold	NU
	TRIGLYCERIDES MEDIUM CHAIN FORMULA							
	<u>Restricted benefit</u>							
	Dietary management of conditions requiring a source of medium chain triglycerides							
	Clinical criteria:							
	Patient must have fat malabsorption due to liver disease; OR							
	Patient must have fat malabsorption due to short gut syndrome; OR							
	Patient must have fat malabsorption due to cystic fibrosis; OR							
	Patient must have fat malabsorption due to gastrointestinal disorders.							
	<u>Note</u>							
	No increase in the maximum number of repeats may be authorised.							
	<u>Note</u>							
	No increase in the maximum quantity or number of units may be authorised.							
	<u>Note</u>							
	Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.							
10152H NP	triglycerides medium chain formula oral liquid: powder for, 400 g	8	5	..	*421.64	37.70	Monogen	SB
10154K NP	triglycerides medium chain formula oral liquid: powder for, 400 g	8	5	..	*411.80	37.70	Peptamen Junior	NT
10155L NP	triglycerides medium chain formula oral liquid: powder for, 400 g	8	5	..	*443.16	37.70	Lipistart	VF
	TRIGLYCERIDES MEDIUM CHAIN FORMULA							
	<u>Restricted benefit</u>							
	Hyperlipoproteinaemia type 1							
	<u>Restricted benefit</u>							
	Long chain fatty acid oxidation disorders							
	<u>Restricted benefit</u>							
	Chylous ascites							
	<u>Restricted benefit</u>							
	Chylothorax							
	<u>Note</u>							
	No increase in the maximum number of repeats may be authorised.							

VARIOUS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	

Note

No increase in the maximum quantity or number of units may be authorised.

Note

Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

1938B NP	triglycerides medium chain formula oral liquid: powder for, 400 g	8	5	..	*443.16	37.70	Lipistart	VF
8478F NP	triglycerides medium chain formula oral liquid: powder for, 400 g	8	5	..	*421.64	37.70	Monogen	SB

Carbohydrates

AMYLOPECTIN MODIFIED LONG CHAIN

Restricted benefit

Glycogen storage disease

9386B NP	amylopectin modified long chain oral liquid: powder for, 30 x 60 g sachets	4	5	..	*752.64	37.70	Glycosade	VF

Milk substitutes

MILK POWDER LACTOSE FREE FORMULA

Authority required

Acute lactose intolerance in infants up to the age of 12 months. The date of birth of the patient must be included in the authority application

Note

No applications for increased maximum quantities and/or repeats will be authorised. No more than 1 application per patient will be authorised.

8282X NP	milk powder lactose free formula oral liquid: powder for, 900 g	5	..	..	*113.21	37.70	S-26 LF	AS

MILK POWDER LACTOSE FREE FORMULA

Authority required

Proven chronic lactose intolerance in infants up to the age of 12 months. The date of birth of the patient must be included in the authority application. Lactose intolerance must have been proven by either:

- (a) relief of symptoms on supervised withdrawal of lactose from the diet for 3 or 4 days and subsequent re-emergence of symptoms on rechallenge with lactose containing formulae or milk or food; or
- (b) not less than 0.5% reducing substance in stool exudate tested with copper sulfate diagnostic compound tablet; or
- (c) hydrogen breath test

Note

No applications for increased maximum quantities and/or repeats will be authorised.

8283Y NP	milk powder lactose free formula oral liquid: powder for, 900 g	5	5	..	*113.21	37.70	S-26 LF	AS

MILK POWDER LACTOSE FREE FORMULA PREDIGESTED

Authority required

Acute lactose intolerance

Population criteria:

Patient must be up to the age of 12 months.

The date of birth of the patient must be included in the authority application.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

No more than 1 application per patient will be authorised.

2975N NP	milk powder lactose free formula predigested oral liquid: powder for, 900 g	5	..	..	*95.76	37.70	Karicare Aptamil Gold De-Lact	NU

MILK POWDER LACTOSE FREE FORMULA PREDIGESTED

Authority required

Chronic lactose intolerance

VARIOUS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
Clinical criteria:								
The condition must be proven to be lactose intolerance.								
Population criteria:								
Patient must be up to the age of 12 months.								
Lactose intolerance must have been proven by either:								
(a) relief of symptoms on supervised withdrawal of lactose from the diet for 3 or 4 days and subsequent re-emergence of symptoms on rechallenge with lactose containing formulae or milk or food; or								
(b) not less than 0.5% reducing substance in stool exudate tested with copper sulfate diagnostic compound tablet; or								
(c) hydrogen breath test.								
The date of birth of the patient must be included in the authority application.								
Note								
No increase in the maximum quantity or number of units may be authorised.								
Note								
No increase in the maximum number of repeats may be authorised.								
2989H NP	milk powder lactose free formula predigested oral liquid: powder for, 900 g	5	5	..	*95.76	37.70	Karicare Aptamil Gold De-Lact	NU
MILK POWDER LACTOSE MODIFIED PREDIGESTED								
Authority required								
Proven chronic lactose intolerance in children aged 1 year and over who are significantly malnourished. The date of birth of the patient must be included in the authority application. Lactose intolerance must have been proven by either:								
(a) relief of symptoms on supervised withdrawal of lactose from the diet for 3 or 4 days and subsequent re-emergence of symptoms on rechallenge with lactose containing formulae or milk or food; or								
(b) not less than 0.5% reducing substance in stool exudate tested with copper sulfate diagnostic compound tablet; or								
(c) hydrogen breath test								
Note								
No applications for increased maximum quantities and/or repeats will be authorised.								
2357C NP	milk powder lactose modified predigested oral liquid: powder for, 900 g	3	10	..	*73.15	37.70	Digestelact	SJ
MILK POWDER LACTOSE MODIFIED PREDIGESTED								
Authority required								
Acute lactose intolerance in children aged 1 year and over. The date of birth of the patient must be included in the authority application								
Note								
No applications for increased maximum quantities and/or repeats will be authorised. No more than 1 application per patient will be authorised.								
2358D NP	milk powder lactose modified predigested oral liquid: powder for, 900 g	3	1	..	*73.15	37.70	Digestelact	SJ
MILK POWDER SYNTHETIC LOW CALCIUM								
Authority required								
Hypercalcaemia in children under the age of 4 years								
Note								
No applications for increased maximum quantities and/or repeats will be authorised.								
3092R NP	milk powder synthetic low calcium oral liquid: powder for, 400 g	8	5	..	*381.72	37.70	Locasol	SB
Other combinations of nutrients								
AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT METHIONINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID								
Restricted benefit								
Pyridoxine non-responsive homocystinuria								
3417W NP	amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without methionine and supplemented with	4	5	..	*2508.32	37.70	HCU Anamix junior LQ	SB

VARIOUS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	docosahexaenoic acid oral liquid, 36 x 125 mL cans							
AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE AND TYROSINE, AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID								
<u>Restricted benefit</u>								
Tyrosinaemia								
9330C NP	amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine and tyrosine, and supplemented with docosahexaenoic acid oral liquid, 36 x 125 mL cans	4	5	..	*2508.32	37.70	TYR Anamix junior LQ	SB
AMINO ACID FORMULA WITHOUT PHENYLALANINE								
<u>Restricted benefit</u>								
Phenylketonuria								
8678R NP	amino acid formula without phenylalanine 1 g tablet, 75	24	5	..	*1427.32	37.70	Phlexy-10	SB
8554F NP	amino acid formula without phenylalanine 500 mg capsule, 200	16	5	..	*1276.68	37.70	Phlexy-10	SB
2347M NP	amino acid formula without phenylalanine oral liquid: powder for, 30 x 20 g sachets	7	5	..	*1463.25	37.70	Phlexy-10 Drink Mix	SB
AMINO ACID FORMULA WITHOUT VALINE, LEUCINE AND ISOLEUCINE								
<u>Restricted benefit</u>								
Maple syrup urine disease								
10161T NP	amino acid formula without valine, leucine and isoleucine containing 5 g of protein equivalent oral liquid: powder for, 30 x 6 g sachets	12	5	..	*3098.68	37.70	MSUD amino5	VF
AMINO ACID FORMULA WITH VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS WITHOUT PHENYLALANINE								
<u>Restricted benefit</u>								
Phenylketonuria								
8479G NP	amino acid formula with vitamins, minerals and long chain polyunsaturated fatty acids without phenylalanine oral liquid: powder for, 400 g	8	5	..	*703.96	37.70	PKU Anamix infant	SB
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN								
<u>Restricted benefit</u>								
A child aged from 6 months up to 10 years with proven glutaric aciduria type 1								
9438R NP	amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 30 x 24 g sachets	4	5	..	*2114.72	37.70	GA gel	VF
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN								
<u>Restricted benefit</u>								
A patient aged 3 years or older with proven glutaric aciduria type 1								
5484P NP	amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 30 x 25 g sachets	4	5	..	*3154.76	37.70	GA express 15	VF
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN								
<u>Restricted benefit</u>								
An infant or young child with proven glutaric aciduria type 1								
2650L NP	amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 400 g	8	5	..	*769.64	37.70	GA1 Anamix infant	SB

VARIOUS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN								
<u>Restricted benefit</u>								
A child aged less than 9 years with proven glutaric aciduria type 1								
2646G NP	amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 500 g	8	5	..	*1785.08	37.70	XLYS, LOW TRY Maxamaid	SB
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE								
<u>Restricted benefit</u>								
Pyridoxine non-responsive homocystinuria								
1548L NP	AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE Oral liquid 125 mL, 30, 1	3	5	..	*3098.68	37.70	HCU Lophlex LQ 20	SB
9133Q NP	amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 130 mL cans	4	5	..	*3098.72	37.70	HCU cooler 15	VF
2640Y NP	amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 174 mL sachets	4	5	..	*4082.72	37.70	HCU cooler 20	VF
2639X NP	amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 87 mL sachets	4	5	..	*2114.72	37.70	HCU cooler 10	VF
8677Q NP	amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 30 x 24 g sachets	4	5	..	*2114.72	37.70	HCU gel	VF
8744F NP	amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 30 x 25 g sachets	4	5	..	*3098.72	37.70	HCU express 15	VF
8328H NP	amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 500 g	8	5	..	*1785.08	37.70	XMET Maxamaid	SB
8416Y NP	amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 500 g	8	5	..	*2705.08	37.70	XMET Maxamum	SB
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE								
<u>Restricted benefit</u>								
For infants and very young children with pyridoxine non-responsive homocystinuria								
8417B NP	amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 400 g	8	5	..	*769.64	37.70	HCU Anamix infant	SB
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, THREONINE AND VALINE AND LOW IN ISOLEUCINE								
<u>Restricted benefit</u>								
Methylmalonic acidemia								
<u>Restricted benefit</u>								
Propionic acidemia								
1923F NP	AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE, THREONINE and VALINE and low in ISOLEUCINE Oral liquid 130 mL, 30, 1	4	5	..	*3098.72	37.70	MMA/PA cooler 15	VF
3444G NP	amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 30 x 24 g sachets	4	5	..	*2114.72	37.70	MMA/PA gel	VF
3443F NP	amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 30 x 25 g sachets	4	5	..	*3098.72	37.70	MMA/PA express 15	VF
8058D NP	amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 400	8	5	..	*769.64	37.70	MMA/PA Anamix infant	SB

VARIOUS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
8059E NP	g amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 500 g	8	5	..	*1785.08	37.70	XMTVI Maxamaid	SB
8061G NP	g amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 500 g	8	5	..	*2705.08	37.70	XMTVI Maxamum	SB
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE								
<u>Restricted benefit</u>								
Phenylketonuria								
1411G NP	AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE Sachets 18.2 g, 60, 1	3	5	..	*1640.41	37.70	add-ins	SB
1909L NP	AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE Sachets 34 g, 30, 1	4	5	..	*2054.36	37.70	PKU express 20	VF
8746H NP	amino acid formula with vitamins and minerals without phenylalanine oral liquid, 18 x 250 mL cans	5	5	..	*1313.61	37.70	Easiphen	SB
9021T NP	amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 125 mL cans	3	5	..	*1549.78	37.70	PKU Lophlex LQ 20	SB
8846N NP	amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 130 mL cans	4	5	..	*1548.68	37.70	PKU Cooler 15	VF
2474F NP	amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 174 mL cans	4	5	..	*2054.36	37.70	PKU Cooler 20	VF
5483N NP	amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 85 g sachets	4	5	..	*1058.96	37.70	PKU squeezeie	VF
2382J NP	amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 87 mL cans	4	5	..	*1035.12	37.70	PKU Cooler 10	VF
9396M NP	amino acid formula with vitamins and minerals without phenylalanine oral liquid, 36 x 125 mL cans	4	5	..	*1270.20	37.70	PKU Anamix Junior LQ	SB
9397N NP	amino acid formula with vitamins and minerals without phenylalanine oral liquid, 60 x 62.5 mL cans	2	5	..	*1059.70	37.70	PKU Lophlex LQ 10	SB
8555G NP	amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 24 g sachets	4	5	..	*1058.96	37.70	PKU gel	VF
8591E NP	amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 25 g sachets	4	5	..	*1549.48	37.70	PKU express 15	VF
8804J NP	amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 27.8 g sachets	3	5	..	*1549.78	37.70	Lophlex	SB
8613H NP	amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 29 g sachets	4	5	..	*892.44	37.70	PKU Anamix Junior	SB
8727H NP	amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 50 g sachets	3	5	..	*1512.40	37.70	XP Maxamum	SB
2738D NP	amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 500 g	8	5	..	*884.36	37.70	XP Maxamaid	SB
2739E NP	amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 500 g	8	5	..	*1352.76	37.70	XP Maxamum	SB
2806Q NP	amino acid formula with vitamins and minerals without phenylalanine oral semi-solid, 36 x 109 g jars	3	5	..	*1853.08	37.70	PKU Lophlex Sensation 20	SB

VARIOUS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE								
<u>Restricted benefit</u>								
Tyrosinaemia								
1547K NP	AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE and TYROSINE Oral liquid 125 mL, 30, 1	3	5	..	*3098.68	37.70	TYR Lophlex LQ 20	SB
9132P NP	amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 130 mL cans	4	5	..	*3098.72	37.70	TYR cooler 15	VF
2701E NP	amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 174 mL sachets	4	5	..	*4082.72	37.70	TYR cooler 20	VF
2674R NP	amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 87 mL sachets	4	5	..	*2114.72	37.70	TYR cooler 10	VF
8631G NP	amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 30 x 24 g sachets	4	5	..	*2114.72	37.70	TYR gel	VF
8667E NP	amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 30 x 25 g sachets	4	5	..	*3098.72	37.70	TYR express 15	VF
9395L NP	amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 30 x 29 g sachets	4	5	..	*1800.80	37.70	TYR Anamix Junior	SB
8445L NP	amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 400 g	8	5	..	*769.64	37.70	TYR Anamix infant	SB
3078B NP	amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 500 g	8	5	..	*2705.08	37.70	XPhen, Tyr Maxamum	SB
8446M NP	amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 500 g	8	5	..	*1785.08	37.70	XPhen, Tyr Maxamaid	SB
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE								
<u>Restricted benefit</u>								
Maple syrup urine disease								
1546J NP	AMINO ACID FORMULA with VITAMINS and MINERALS without VALINE, LEUCINE and ISOLEUCINE Oral liquid 125 mL, 30, 1	3	5	..	*3098.68	37.70	MSUD Lophlex LQ 20	SB
1914R NP	AMINO ACID FORMULA with VITAMINS and MINERALS without VALINE, LEUCINE and ISOLEUCINE Sachets 34 g, 30, 1	4	5	..	*4094.48	37.70	MSUD express 20	VF
2375B NP	amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 130 mL cans	4	5	..	*3098.72	37.70	MSUD cooler 15	VF
2654Q NP	amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 174 mL pouches	4	5	..	*4082.72	37.70	MSUD cooler 20	VF
2651M NP	amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 87 mL pouches	4	5	..	*2114.72	37.70	MSUD cooler 10	VF
8592F NP	amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 30 x 24 g sachets	4	5	..	*2114.72	37.70	MSUD gel	VF
8632H	amino acid formula with vitamins and	4	5	..	*3098.72	37.70	MSUD express 15	VF

VARIOUS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
NP	minerals without valine, leucine and isoleucine oral liquid: powder for, 30 x 25 g sachets							
8745G NP	amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 30 x 29 g sachets	4	5	..	*1800.80	37.70	MSUD Anamix Junior	SB
2380G NP	amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 400 g	8	5	..	*769.64	37.70	MSUD Anamix infant	SB
8057C NP	amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 500 g	8	5	..	*2705.08	37.70	MSUD Maxamum	SB
8260R NP	amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 500 g	8	5	..	*1785.08	37.70	MSUD Maxamaid	SB
8310J NP	amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 500 g	4	5	..	*2672.32	37.70	MSUD AID III	SB
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE WITH FAT, CARBOHYDRATE AND TRACE ELEMENTS AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID								
<u>Restricted benefit</u>								
Maple syrup urine disease								
9499Y NP	amino acid formula with vitamins and minerals without valine, leucine and isoleucine with fat, carbohydrate and trace elements and supplemented with docosahexaenoic acid oral liquid, 36 cans	4	5	..	*2508.32	37.70	MSUD Anamix Junior LQ	SB
ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID WITH CARBOHYDRATE								
<u>Authority required</u>								
Peroxisomal biogenesis disorders								
10036F NP	arachidonic acid and docosahexaenoic acid with carbohydrate containing 200 mg arachidonic acid and 100 mg docosahexaenoic acid oral liquid: powder for, 30 x 4 g sachets	4	5	..	*371.16	37.70	keyomega	VF
ARGININE WITH CARBOHYDRATE								
<u>Restricted benefit</u>								
Urea cycle disorders								
<u>Note</u>								
Arginine with carbohydrate is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism.								
5482M NP	arginine with carbohydrate containing 2 g arginine oral liquid: powder for, 30 x 4 g sachets	4	5	..	*771.16	37.70	Arginine 2000	VF
10093F NP	arginine with carbohydrate containing 5 g arginine oral liquid: powder for, 30 x 7.6 g sachets	4	5	..	*1023.44	37.70	Arginine 5000	VF
9437Q NP	arginine with carbohydrate containing 500 mg arginine oral liquid: powder for, 30 x 4 g sachets	4	5	..	*516.36	37.70	Arginine 500	VF
CARBOHYDRATE, FAT, VITAMINS, MINERALS AND TRACE ELEMENTS								
<u>Restricted benefit</u>								
Proven inborn errors of protein metabolism								
Clinical criteria:								
Patient must be unable to meet their energy requirements with permitted food and formulae.								
8369L NP	carbohydrate, fat, vitamins, minerals and trace elements oral liquid: powder for, 400 g	8	5	..	*318.52	37.70	Energivit	SB

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
CARBOHYDRATES, FAT, VITAMINS, MINERALS, TRACE ELEMENTS AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID							
	<u>Restricted benefit</u>						
	Proven inborn errors of protein metabolism						
	Clinical criteria:						
	Patient must be unable to meet their energy requirements with permitted food and formulae.						
10050Y <i>NP</i>	carbohydrates, fat, vitamins, minerals, trace elements and supplemented with arachidonic acid and docosahexaenoic acid providing 100 kilocalories oral liquid: powder for 30 x 21.5 g sachets	4	5	..	*248.60	37.70	basecal 100 VF
10039J <i>NP</i>	carbohydrates, fat, vitamins, minerals, trace elements and supplemented with arachidonic acid and docosahexaenoic acid providing 200 kilocalories oral liquid: powder for, 30 x 43 g sachets	4	5	..	*472.48	37.70	basecal 200 VF
CITRULLINE WITH CARBOHYDRATE							
	<u>Restricted benefit</u>						
	Urea cycle disorders in order to prevent low plasma arginine or citrulline levels						
	Note						
	Citrulline with carbohydrate is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism.						
5481L <i>NP</i>	citrulline with carbohydrate containing 1 g citrulline oral liquid: powder for, 30 x 4 g sachets	4	5	..	*516.36	37.70	Citrulline 1000 VF
CYSTINE WITH CARBOHYDRATE							
	<u>Restricted benefit</u>						
	Pyridoxine non-responsive homocystinuria						
9164H <i>NP</i>	cystine with carbohydrate containing 500 mg cystine oral liquid: powder for, 30 x 4 g sachets	4	5	..	*516.36	37.70	Cystine 500 VF
DOCOSAHEXAENOIC ACID WITH CARBOHYDRATE							
	<u>Authority required</u>						
	Peroxisomal biogenesis disorders						
10040K <i>NP</i>	docosahexaenoic acid with carbohydrate containing 200 mg docosahexaenoic acid oral liquid: powder for, 30 x 4g sachets	4	5	..	*371.16	37.70	docomega VF
ESSENTIAL AMINO ACIDS FORMULA							
	<u>Restricted benefit</u>						
	Gyrate atrophy of the choroid and retina						
	<u>Restricted benefit</u>						
	Urea cycle disorders						
9329B <i>NP</i>	essential amino acids formula oral liquid: powder for, 2 x 200 g cans	6	5	..	*1200.88	37.70	Essential Amino Acid Mix SB
ESSENTIAL AMINO ACIDS FORMULA WITH MINERALS AND VITAMIN C							
	<u>Restricted benefit</u>						
	Gyrate atrophy of the choroid and retina						
	<u>Restricted benefit</u>						
	Urea cycle disorders						
2027Q <i>NP</i>	essential amino acids formula with minerals and vitamin C oral liquid: powder for, 400 g	5	5	..	*634.51	37.70	Dialamine SB
ESSENTIAL AMINO ACIDS FORMULA WITH VITAMINS AND MINERALS							
	<u>Restricted benefit</u>						
	Gyrate atrophy of the choroid and retina						

VARIOUS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
<u>Restricted benefit</u>								
Urea cycle disorders								
9385Y NP	essential amino acids formula with vitamins and minerals oral liquid: powder for, 50 x 12.5 g sachets	4	5	..	*1516.84	37.70	EAA Supplement	VF
GLYCINE WITH CARBOHYDRATE								
<u>Restricted benefit</u>								
Isovaleric acidaemia								
10195N NP	glycine with carbohydrate containing 500 mg of glycine oral liquid: powder for, 30 x 4 g sachets	4	5	..	*516.36	37.70	Glycine500	VF
GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS								
<u>Restricted benefit</u>								
Phenylketonuria								
2712R NP	glycomacropeptide and essential amino acids oral liquid, 12 x 500 mL bottles	12	5	..	*1270.48	37.70	Camino Pro Restore	QH
GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS								
<u>Restricted benefit</u>								
Phenylketonuria								
2696X NP	glycomacropeptide and essential amino acids with vitamins and minerals bar, 7 x 54 g	14	5	..	*866.78	37.70	Camino Pro Complete	QH
2644E NP	glycomacropeptide and essential amino acids with vitamins and minerals bar, 7 x 81 g	14	5	..	*1296.86	37.70	Camino Pro Complete	QH
2685H NP	glycomacropeptide and essential amino acids with vitamins and minerals oral liquid: powder for, 28 x 49 g sachets	4	5	..	*1480.12	37.70	Camino Pro Bettermilk	QH
HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE								
<u>Restricted benefit</u>								
Ketogenic diet								
Clinical criteria:								
Patient must have intractable seizures requiring treatment with a ketogenic diet; OR								
Patient must have a glucose transport protein defect; OR								
Patient must have pyruvate dehydrogenase deficiency.								
KetoCal 3:1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.								
<u>Note</u>								
Authorities for increased maximum quantities, up to a maximum of 48, may be authorised.								
2652N NP	high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (3:1 ratio long chain fat to carbohydrate plus protein) oral liquid: powder for, 300 g	24	5	..	*1037.80	37.70	KetoCal 3:1	SB
HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE								
<u>Restricted benefit</u>								
Ketogenic diet								
Clinical criteria:								
Patient must have intractable seizures requiring treatment with a ketogenic diet; OR								
Patient must have a glucose transport protein defect; OR								
Patient must have pyruvate dehydrogenase deficiency.								
KetoCal 4:1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.								
<u>Note</u>								
Authorities for increased maximum quantities, up to a maximum of 11, may be authorised.								
10185C NP	high fat formula with vitamins, minerals and trace elements and low in protein	5	5	..	*987.31	37.70	KetoCal 4:1 LQ	SB

VARIOUS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	and carbohydrate (4:1 ratio long chain fat to carbohydrate plus protein) oral liquid, 32 x 200 mL cartons							
HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE								
<u>Restricted benefit</u>								
Ketogenic diet								
Clinical criteria:								
Patient must have intractable seizures requiring treatment with a ketogenic diet; OR								
Patient must have a glucose transport protein defect; OR								
Patient must have pyruvate dehydrogenase deficiency.								
KetoCal 4:1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.								
<u>Note</u>								
Authorities for increased maximum quantities, up to a maximum of 48, may be authorised.								
9446E NP	high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (4:1 ratio long chain fat to carbohydrate plus protein) oral liquid: powder for, 300 g	24	5	..	*1037.80	37.70	KetoCal 4:1	SB
ISOLEUCINE WITH CARBOHYDRATE								
<u>Restricted benefit</u>								
Maple syrup urine disease								
9436P NP	isoleucine with carbohydrate containing 1 g isoleucine oral liquid: powder for, 30 x 4 g sachets	4	5	..	*567.32	37.70	Isoleucine 1000	VF
9134R NP	isoleucine with carbohydrate containing 50 mg isoleucine oral liquid: powder for, 30 x 4 g sachets	4	5	..	*516.36	37.70	Isoleucine 50	VF
MILK PROTEIN AND FAT FORMULA WITH VITAMINS AND MINERALS CARBOHYDRATE FREE								
<u>Restricted benefit</u>								
Patients with intractable seizures requiring treatment with a ketogenic diet								
<u>Restricted benefit</u>								
Glucose transport protein defects								
<u>Restricted benefit</u>								
Pyruvate dehydrogenase deficiency								
<u>Restricted benefit</u>								
Infants and young children with glucose-galactose intolerance and multiple monosaccharide intolerance								
8630F NP	milk protein and fat formula with vitamins and minerals carbohydrate free oral liquid: powder for, 225 g	24	5	..	*648.76	37.70	Carbohydrate Free Mixture	SB
PHENYLALANINE WITH CARBOHYDRATE								
<u>Restricted benefit</u>								
Tyrosinaemia								
9384X NP	phenylalanine with carbohydrate containing 50 mg phenylalanine oral liquid: powder for, 30 x 4 g sachets	4	5	..	*516.36	37.70	Phenylalanine 50	VF
SOY PROTEIN AND FAT FORMULA WITH VITAMINS AND MINERALS CARBOHYDRATE FREE								
<u>Restricted benefit</u>								
Patients with intractable seizures requiring treatment with a ketogenic diet								
<u>Restricted benefit</u>								
Glucose transport protein defects								
<u>Restricted benefit</u>								
Pyruvate dehydrogenase deficiency								
<u>Restricted benefit</u>								
Infants and young children with glucose-galactose intolerance and multiple monosaccharide intolerance								
8577K NP	soy protein and fat formula with vitamins and minerals carbohydrate free oral liquid, 1 x 384 mL can	120	5	..	*670.36	37.70	RCF	AB

VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE

VARIOUS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
Authority required								
Infants and children whose vitamin and mineral intake is insufficient due to a specific diagnosis requiring a highly restrictive therapeutic diet, and whose vitamin, mineral and trace element needs cannot be adequately met with other proprietary vitamin and mineral preparations								
Note								
Paediatric Seravit should only be used under strict supervision of a dietitian and a paediatrician.								
9328Y NP	vitamins, minerals and trace elements with carbohydrate oral liquid: powder for, 200 g	6	5	..	*390.76	37.70	Paediatric Seravit	SB
VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE								
Authority required								
Dietary management of conditions requiring a highly restrictive therapeutic diet								
Clinical criteria:								
Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet,								
AND								
Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations.								
Population criteria:								
Patient must be aged 3 years or older.								
Note								
FruitiVits must only be used under strict supervision of a dietitian and a paediatrician.								
10149E NP	vitamins, minerals and trace elements with carbohydrate oral liquid: powder for, 30 x 6 g sachets	1	5	..	299.25	37.70	FruitiVits	VF
WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, LONG CHAIN POLYUNSATURATED FATTY ACIDS, VITAMINS AND MINERALS, LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE								
Authority required								
Chronic renal failure								
Clinical criteria:								
Patient must require treatment with a low protein and a low phosphorus diet; OR								
Patient must require treatment with a low protein, low phosphorus and low potassium diet.								
Population criteria:								
Patient must be an infant or a young child.								
9382T NP	whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, low in protein, phosphate, potassium and lactose oral liquid: powder for, 10 x 100 g sachets	9	5	..	*1485.91	37.70	RenaStart	VF
2870C NP	whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, low in protein, phosphate, potassium and lactose oral liquid: powder for, 6 x 400 g cans	4	5	..	*1584.60	37.70	Renastart	VF
WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, VITAMINS AND MINERALS, AND LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE								
Authority required								
Infants and young children with chronic renal failure requiring treatment with a low protein and a low phosphorus diet, or a low protein, a low phosphorus and a low potassium diet								
8587Y NP	whey protein formula supplemented with amino acids, vitamins and minerals, and low in protein, phosphate, potassium and lactose oral liquid: powder for, 400 g	16	5	..	*1066.28	37.70	Kindergen	SB

Pharmaceutical Benefits for Palliative Care

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	

ALIMENTARY TRACT AND METABOLISM

STOMATOLOGICAL PREPARATIONS

STOMATOLOGICAL PREPARATIONS

Other agents for local oral treatment

BENZYDAMINE

Authority required (STREAMLINED)

3634

Initial supply, for up to 4 months, for a palliative care patient where a painful mouth is a problem

5385K NP	benzydamine hydrochloride 0.15% mouthwash, 500 mL	‡1	3	..	22.60	23.75	Difflam	IA

BENZYDAMINE

Authority required (STREAMLINED)

3635

Continuing supply for a palliative care patient where a painful mouth is a problem

Note

Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

5386L NP	benzydamine hydrochloride 0.15% mouthwash, 500 mL	‡1	..	..	22.60	23.75	Difflam	IA

DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

BELLADONNA AND DERIVATIVES, PLAIN

Belladonna alkaloids, semisynthetic, quaternary ammonium compounds

HYOSCINE BUTYLBROMIDE

Authority required (STREAMLINED)

3638

Initial supply, for up to 4 months, for a palliative care patient where colicky pain is a symptom

5317W NP	hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules	6	3	..	*108.88	37.70	Buscopan	BY

HYOSCINE BUTYLBROMIDE

Authority required (STREAMLINED)

3639

Continuing supply for a palliative care patient where colicky pain is a symptom

Note

Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

5318X NP	hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules	6	..	..	*108.88	37.70	Buscopan	BY

DRUGS FOR CONSTIPATION

DRUGS FOR CONSTIPATION

Contact laxatives

BISACODYL

Authority required (STREAMLINED)

3642

Initial supply, for up to 4 months, for a palliative care patient where constipation is a problem

5303D NP	bisacodyl 10 mg suppository, 10	3	3	..	*21.28	22.43	^a Petrus Bisacodyl Suppositories	PP
				^B 1.50	*22.78	22.43	^a Dulcolax	BY
5304E NP	bisacodyl 10 mg suppository, 12	3	3	..	*18.67	19.82	Petrus Bisacodyl Suppositories	PP
5301B NP	bisacodyl 5 mg tablet: enteric, 200 tablets	1	3	..	14.45	15.60	Bisalax	AS

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							Lax-Tab	AE
BISACODYL								
<u>Authority required (STREAMLINED)</u>								
3643								
Continuing supply for a palliative care patient where constipation is a problem								
<u>Note</u>								
Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.								
5307H NP	bisacodyl 10 mg suppository, 10	3	..	..	*21.28	22.43	^a Petrus Bisacodyl Suppositories	PP
				^B 1.50	*22.78	22.43	^a Dulcolax	BY
5308J NP	bisacodyl 10 mg suppository, 12	3	..	..	*18.67	19.82	Petrus Bisacodyl Suppositories	PP
5305F NP	bisacodyl 5 mg tablet: enteric, 200 tablets	1	..	..	14.45	15.60	Bisalax	AS
							Lax-Tab	AE

Bulk-forming laxatives

RHAMNUS FRANGULA + STERCULIA

Authority required (STREAMLINED)

3642

Initial supply, for up to 4 months, for a palliative care patient where constipation is a problem

5322D NP	rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g	±1	3	..	26.71	27.86	Normacol Plus	NE

RHAMNUS FRANGULA + STERCULIA

Authority required (STREAMLINED)

3643

Continuing supply for a palliative care patient where constipation is a problem

Note

Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

5324F NP	rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g	±1	..	..	26.71	27.86	Normacol Plus	NE

Osmotically acting laxatives

LACTULOSE

Authority required (STREAMLINED)

3642

Initial supply, for up to 4 months, for a palliative care patient where constipation is a problem

5387M NP	LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1	3	3	..	*18.58	19.73	^a Genlac	QA
				^B 2.67	*21.25	19.73	^a Actilax	AF
							^a Dulose	FM

LACTULOSE

Authority required (STREAMLINED)

3643

Continuing supply for a palliative care patient where constipation is a problem

Note

Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

5388N NP	LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1	3	..	..	*18.58	19.73	^a Genlac	QA
				^B 2.67	*21.25	19.73	^a Actilax	AF
							^a Dulose	FM

MACROGOL-3350

Authority required (STREAMLINED)

4176

Constipation

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Treatment Phase: Initial treatment							
	Clinical criteria:							
	Patient must be receiving palliative care,							
	AND							
	Patient must not receive more than 4 months treatment under this restriction.							
	Note							
	Pharmaceutical benefits that have the form macrogol-3350 1 g/g oral liquid: powder for, 510 g and pharmaceutical benefits that have the form macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets are equivalent for the purposes of substitution.							
2351R NP	macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets	2	3	..	*30.38	31.53	^a Herron ClearLax	ON
5426N NP	macrogol-3350 1 g/g oral liquid: powder for, 510 g	2	3	..	*30.38	31.53	^a OsmoLax	KY
	MACROGOL-3350							
	Authority required (STREAMLINED)							
	4170							
	Constipation							
	Treatment Phase: Continuing treatment							
	Clinical criteria:							
	Patient must be receiving palliative care.							
	Note							
	Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.							
	Note							
	Pharmaceutical benefits that have the form macrogol-3350 1 g/g oral liquid: powder for, 510 g and pharmaceutical benefits that have the form macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets are equivalent for the purposes of substitution.							
2353W NP	macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets	2	..	..	*30.38	31.53	^a Herron ClearLax	ON
5427P NP	macrogol-3350 1 g/g oral liquid: powder for, 510 g	2	..	..	*30.38	31.53	^a OsmoLax	KY
	MACROGOL-3350 + SODIUM CHLORIDE + POTASSIUM CHLORIDE + BICARBONATE							
	Authority required (STREAMLINED)							
	4595							
	Constipation							
	Treatment Phase: Initial treatment							
	Clinical criteria:							
	Patient must be receiving palliative care,							
	AND							
	Patient must not receive more than 4 months treatment under this restriction.							
5389P NP	macrogol-3350 13.12 g + sodium chloride 350.7 mg + potassium chloride 46.6 mg (0.63 mmol potassium) + sodium bicarbonate 178.5 mg solution, 30 sachets	2	3	..	*30.38	31.53	^a APO-MACROGOL plus ELECTROLYTES	TX
							^a LaxaCon	GN
							^a lax-sachets	AE
							^a Macrovic	QA
							^a Molaxole	HM
							^a Movicol	NE
10127B NP	macrogol-3350 13.12 g/25 mL + sodium chloride 350.7 mg/25 mL + potassium chloride 46.6 mg/25 mL (0.63 mmol/25 mL potassium) + sodium bicarbonate 178.5 mg/25 mL oral liquid, 500 mL	2	3	..	*22.52	23.67	Movicol Liquid	NE
	MACROGOL-3350 + SODIUM CHLORIDE + POTASSIUM CHLORIDE + BICARBONATE							
	Authority required (STREAMLINED)							
	4590							

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Constipation							
	Treatment Phase: Continuing treatment							
	Clinical criteria:							
	Patient must be receiving palliative care.							
	Note							
	Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.							
5390Q NP	macrogol-3350 13.12 g + sodium chloride 350.7 mg + potassium chloride 46.6 mg (0.63 mmol potassium) + sodium bicarbonate 178.5 mg solution, 30 sachets	2	..	..	*30.38	31.53	^a APO-MACROGOL plus ELECTROLYTES	TX
							^a LaxaCon	GN
							^a lax-sachets	AE
							^a Macrovic	QA
							^a Molaxole	HM
							^a Movicol	NE
10112F NP	macrogol-3350 13.12 g/25 mL + sodium chloride 350.7 mg/25 mL + potassium chloride 46.6 mg/25 mL (0.63 mmol/25 mL potassium) + sodium bicarbonate 178.5 mg/25 mL oral liquid, 500 mL	2	..	..	*22.52	23.67	Movicol Liquid	NE

Enemas

BISACODYL

Authority required (STREAMLINED)

3642

Initial supply, for up to 4 months, for a palliative care patient where constipation is a problem

5302C NP	bisacodyl 10 mg/5 mL enema, 25 x 5 mL	1	3	..	38.28	37.70	Bisalax	AS

BISACODYL

Authority required (STREAMLINED)

3643

Continuing supply for a palliative care patient where constipation is a problem

Note

Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

5306G NP	bisacodyl 10 mg/5 mL enema, 25 x 5 mL	1	..	..	38.28	37.70	Bisalax	AS

SORBITOL + CITRATE + LAURYL SULFOACETATE SODIUM

Authority required (STREAMLINED)

3642

Initial supply, for up to 4 months, for a palliative care patient where constipation is a problem

5331N NP	sorbitol 3.125 g/5 mL + citrate sodium dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 12 x 5 mL	2	3	..	*32.62	33.77	^a Micolette	AE
							^a Microlax	JT

SORBITOL + CITRATE + LAURYL SULFOACETATE SODIUM

Authority required (STREAMLINED)

3643

Continuing supply for a palliative care patient where constipation is a problem

Note

Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

5332P NP	sorbitol 3.125 g/5 mL + citrate sodium dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 12 x 5 mL	2	..	..	*32.62	33.77	^a Micolette	AE

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							^a Microlax	JT

Peripheral opioid receptor antagonists

METHYLNALTREXONE

Authority required

Continuing supply, in combination with oral laxatives, for a palliative care patient with opioid-induced constipation who has demonstrated a response to methylnaltrexone

Note

For first continuing supply, applications for increased repeats may be authorised.

Where consultation with a palliative care specialist or service has occurred, applications for increased repeats may be authorised.

Note

Special Pricing Arrangements apply.

5424L NP	METHYLNALTREXONE Solution for injection containing methylnaltrexone bromide 12 mg in 0.6 mL, 7	1	..	..	288.18	37.70	Relistor	LM

METHYLNALTREXONE

Authority required

Initial supply, in combination with oral laxatives, for a palliative care patient with opioid-induced constipation who has failed to respond to laxatives

Note

No applications for repeats will be authorised.

Note

Special Pricing Arrangements apply.

5423K NP	methylnaltrexone bromide 12 mg/0.6 mL injection, 1 x 0.6 mL vial	3	..	..	*130.93	37.70	Relistor	LM

Other drugs for constipation

GLYCEROL

Authority required (STREAMLINED)

3642

Initial supply, for up to 4 months, for a palliative care patient where constipation is a problem

5312N NP	glycerol 1.4 g suppository, 12	3	3	..	*21.55	22.70	Petrus Pharmaceuticals Pty Ltd	PP
5313P NP	glycerol 2.8 g suppository, 12	3	3	..	*22.15	23.30	Petrus Pharmaceuticals Pty Ltd	PP
5311M NP	glycerol 700 mg suppository, 12	3	3	..	*21.10	22.25	Petrus Pharmaceuticals Pty Ltd	PP

GLYCEROL

Authority required (STREAMLINED)

3643

Continuing supply for a palliative care patient where constipation is a problem

Note

Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

5315R NP	glycerol 1.4 g suppository, 12	3	..	..	*21.55	22.70	Petrus Pharmaceuticals Pty Ltd	PP
5316T NP	glycerol 2.8 g suppository, 12	3	..	..	*22.15	23.30	Petrus Pharmaceuticals Pty Ltd	PP
5314Q NP	glycerol 700 mg suppository, 12	3	..	..	*21.10	22.25	Petrus Pharmaceuticals Pty Ltd	PP

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	

MUSCULO-SKELETAL SYSTEM

ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS

ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS

Acetic acid derivatives and related substances

DICLOFENAC

Authority required

Initial supply, for up to 4 months, for a palliative care patient where severe pain is a problem

5363G NP	diclofenac sodium 100 mg suppository, 20	2	3	..	*25.26	26.41	Voltaren 100	NV

DICLOFENAC

Authority required

Continuing supply for a palliative care patient where severe pain is a problem

Note

Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

5366K NP	diclofenac sodium 100 mg suppository, 20	2	..	..	*25.26	26.41	Voltaren 100	NV

DICLOFENAC

Authority required (STREAMLINED)

3645

Initial supply, for up to 4 months, for a palliative care patient where severe pain is a problem

5361E NP	diclofenac sodium 25 mg tablet: enteric, 50 tablets	2	3	..	*10.62	11.77	^a APO-Diclofenac	TX
							^a Chem mart Diclofenac	CH
							^a Clonac 25	QA
							^a Diclofenac AN	EA
							^a Diclofenac-GA	GN
							^a Diclofenac Sandoz	SZ
							^a Fenac 25	AF
							^a Terry White Chemists Diclofenac	TW
				^B 1.44	*12.06	11.77	^a Voltaren 25	NV
5362F NP	diclofenac sodium 50 mg tablet: enteric, 50 tablets	1	3	..	9.44	10.59	^a APO-Diclofenac	TX
							^a Chem mart Diclofenac	CH
							^a Clonac 50	QA
							^a Diclofenac AN	EA
							^a Diclofenac-GA	GN
							^a Diclofenac Sandoz	SZ
							^a Fenac	AF
							^a Terry White Chemists Diclofenac	TW
				^B 1.43	10.87	10.59	^a Voltaren 50	NV

DICLOFENAC

Authority required (STREAMLINED)

3646

Continuing supply for a palliative care patient where severe pain is a problem

Note

Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

5364H NP	diclofenac sodium 25 mg tablet: enteric, 50 tablets	2	..	..	*10.62	11.77	^a APO-Diclofenac	TX
							^a Chem mart Diclofenac	CH
							^a Clonac 25	QA
							^a Diclofenac AN	EA

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$		Brand Name and Manufacturer	
5365J NP	diclofenac sodium 50 mg tablet: enteric, 50 tablets	1	..	..	9.44	10.59		a Diclofenac-GA	GN
								a Diclofenac Sandoz	SZ
								a Fenac 25	AF
								a Terry White Chemists Diclofenac	TW
								a Voltaren 25	NV
								a APO-Diclofenac	TX
								a Chem mart Diclofenac	CH
								a Clonac 50	QA
								a Diclofenac AN	EA
								a Diclofenac-GA	GN
								a Diclofenac Sandoz	SZ
								a Fenac	AF
								a Terry White Chemists Diclofenac	TW
								B1.43	10.87
INDOMETHACIN									
<u>Authority required</u>									
Initial supply, for up to 4 months, for a palliative care patient where severe pain is a problem									
5378C NP	indomethacin 100 mg suppository, 20	2	3	..	*22.84	23.99		Indocid	AS
INDOMETHACIN									
<u>Authority required</u>									
Continuing supply for a palliative care patient where severe pain is a problem									
<u>Note</u>									
Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.									
5380E NP	indomethacin 100 mg suppository, 20	2	..	..	*22.84	23.99		Indocid	AS
INDOMETHACIN									
<u>Authority required (STREAMLINED)</u>									
3645									
Initial supply, for up to 4 months, for a palliative care patient where severe pain is a problem									
5377B NP	indomethacin 25 mg capsule, 50	2	3	..	*13.20	14.35	a	Arthrexin	AF
					B4.64	*17.84	14.35	a	Indocid
INDOMETHACIN									
<u>Authority required (STREAMLINED)</u>									
3646									
Continuing supply for a palliative care patient where severe pain is a problem									
<u>Note</u>									
Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.									
5379D NP	indomethacin 25 mg capsule, 50	2	..	..	*13.20	14.35	a	Arthrexin	AF
					B4.64	*17.84	14.35	a	Indocid

Propionic acid derivatives

IBUPROFEN

Authority required

Initial supply, for up to 4 months, for a palliative care patient where severe pain is a problem

5368M NP	ibuprofen 400 mg tablet, 30	3	3	..	*15.07	16.22	Brufen	GO

IBUPROFEN

Authority required

Continuing supply for a palliative care patient where severe pain is a problem

Note

[illegible]

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
Clinical criteria:								
Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent.								
Treatment criteria:								
Patient must be undergoing palliative care.								
Note								
Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.								
5398D NP	naproxen 125 mg/5 mL oral liquid, 474 mL	1	..	..	127.96	37.70	Phebra Naproxen Suspension	PL
NAPROXEN								
Authority required (STREAMLINED)								
3645								
Initial supply, for up to 4 months, for a palliative care patient where severe pain is a problem								
Note								
Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.								
5353R NP	naproxen sodium 550 mg tablet, 50	1	3	..	13.11	14.26	^a Crysanal	MD
				^b 2.17	15.28	14.26	^a Anaprox 550	RO
NAPROXEN								
Authority required (STREAMLINED)								
3646								
Continuing supply for a palliative care patient where severe pain is a problem								
Note								
Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.								
Note								
Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.								
5354T NP	naproxen sodium 550 mg tablet, 50	1	..	..	13.11	14.26	^a Crysanal	MD
				^b 2.17	15.28	14.26	^a Anaprox 550	RO

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

NERVOUS SYSTEM

ANALGESICS

OPIOIDS

Natural opium alkaloids

MORPHINE

Authority required

Initial supply, for up to 3 months, for a palliative care patient with severe disabling pain not responding to non-narcotic analgesics

Caution

The risk of drug dependence is high.

Note

Telephone approvals are limited to 1 month's therapy.

5393W NP	morphine sulfate 10 mg tablet, 20	1	2	..	14.66	15.81	Sevredol	MF
5394X NP	morphine sulfate 20 mg tablet, 20	1	2	..	15.60	16.75	Sevredol	MF

MORPHINE

Authority required

Continuing supply for a palliative care patient with severe disabling pain not responding to non-narcotic analgesics

Caution

The risk of drug dependence is high.

Note

Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.

Telephone approvals are limited to 1 month's therapy.

5395Y NP	morphine sulfate 10 mg tablet, 20	1	..	..	14.66	15.81	Sevredol	MF
5396B NP	morphine sulfate 20 mg tablet, 20	1	..	..	15.60	16.75	Sevredol	MF

MORPHINE

Authority required

Initial supply, for up to 3 months, for a palliative care patient with chronic severe disabling pain not responding to non-narcotic analgesics

Caution

The risk of drug dependence is high.

Note

Telephone approvals are limited to 1 month's therapy.

5391R NP	morphine sulfate 200 mg tablet: modified release, 28 tablets	1	2	..	122.20	37.70	MS Contin	MF

MORPHINE

Authority required

Continuing supply for a palliative care patient with chronic severe disabling pain not responding to non-narcotic analgesics

Caution

The risk of drug dependence is high.

Note

Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.

Telephone approvals are limited to 1 month's therapy.

5392T NP	morphine sulfate 200 mg tablet: modified release, 28 tablets	1	..	..	122.20	37.70	MS Contin	MF

Phenylpiperidine derivatives

FENTANYL

Authority required

Breakthrough pain

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
Treatment Phase: Continuing treatment								
Clinical criteria:								
Patient must have cancer,								
AND								
Patient must be receiving opioids for their persistent pain,								
AND								
Patient must be unable to tolerate further escalation in the dose of morphine for breakthrough pain due to adverse effects.								
Treatment criteria:								
Patient must be undergoing palliative care.								
Caution								
The risk of drug dependence is high.								
Note								
For first continuing supply, applications for increased repeats for up to 3 months' supply may be authorised.								
Note								
Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.								
Note								
Telephone approvals are limited to 1 months' therapy.								
Note								
Shared Care Model:								
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
5411T NP	FENTANYL Lozenge 1200 micrograms (as citrate), 30	2	..	..	*579.77	37.70	Actiq	OA
5412W NP	FENTANYL Lozenge 1600 micrograms (as citrate), 30	2	..	..	*579.77	37.70	Actiq	OA
5407N NP	FENTANYL Lozenge 200 micrograms (as citrate), 30	2	..	..	*579.77	37.70	Actiq	OA
5408P NP	FENTANYL Lozenge 400 micrograms (as citrate), 30	2	..	..	*579.77	37.70	Actiq	OA
5409Q NP	FENTANYL Lozenge 600 micrograms (as citrate), 30	2	..	..	*579.77	37.70	Actiq	OA
5410R NP	FENTANYL Lozenge 800 micrograms (as citrate), 30	2	..	..	*579.77	37.70	Actiq	OA
FENTANYL								
Authority required								
Breakthrough pain								
Treatment Phase: Initial treatment for dose titration								
Clinical criteria:								
Patient must have cancer,								
AND								
Patient must be receiving opioids for their persistent pain,								
AND								
Patient must be unable to tolerate further escalation in the dose of morphine for breakthrough pain due to adverse effects.								
Treatment criteria:								
Patient must be undergoing palliative care.								
Caution								
The risk of drug dependence is high.								
Note								
No increase in the maximum number of repeats may be authorised.								
Note								
Shared Care Model:								
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
5405L	FENTANYL Lozenge 1200 micrograms	1	..	..	99.95	37.70	Actiq	OA

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
NP	(as citrate), 9							
5406M	FENTANYL Lozenge 1600 micrograms	1	..	..	99.95	37.70	Actiq	OA
NP	(as citrate), 9							
5401G	FENTANYL Lozenge 200 micrograms (as citrate), 9	1	..	..	99.95	37.70	Actiq	OA
NP								
5402H	FENTANYL Lozenge 400 micrograms (as citrate), 9	1	..	..	99.95	37.70	Actiq	OA
NP								
5403J	FENTANYL Lozenge 600 micrograms (as citrate), 9	1	..	..	99.95	37.70	Actiq	OA
NP								
5404K	FENTANYL Lozenge 800 micrograms (as citrate), 9	1	..	..	99.95	37.70	Actiq	OA
NP								

Diphenylpropylamine derivatives

METHADONE

Authority required

Initial supply, for up to 3 months, for a palliative care patient with chronic severe disabling pain not responding to non-narcotic analgesics

Caution

The risk of drug dependence is high.

Note

Telephone approvals are limited to 1 month's therapy.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

5399E	methadone hydrochloride 5 mg/mL oral liquid, 200 mL	1	2	..	19.25	20.40	Aspen Methadone Syrup	QA
NP								

METHADONE

Authority required

Continuing supply for a palliative care patient with chronic severe disabling pain not responding to non-narcotic analgesics

Caution

The risk of drug dependence is high.

Note

Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.

Telephone approvals are limited to 1 month's therapy.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

5400F	methadone hydrochloride 5 mg/mL oral liquid, 200 mL	1	..	..	19.25	20.40	Aspen Methadone Syrup	QA
NP								

OTHER ANALGESICS AND ANTIPYRETICS

Anilides

PARACETAMOL

Authority required (STREAMLINED)

3649

Initial supply, for up to 4 months, for a palliative care patient for analgesia or fever where alternative therapy cannot be tolerated

5319Y	paracetamol 500 mg suppository, 24	4	3	..	*84.80	37.70	Panadol	GC
NP								
5343F	paracetamol 665 mg tablet: modified release, 96 tablets	2	3	..	*15.34	16.49	^a Osteomol 665 Paracetamol	CR
NP				^B 1.64	*16.98	16.49	^a Panadol Osteo	GC

PARACETAMOL

Authority required (STREAMLINED)

3650

Continuing supply for a palliative care patient for analgesia or fever where alternative therapy cannot be tolerated

Note

Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	occurred.							
5320B NP	paracetamol 500 mg suppository, 24	4	..	..	*84.80	37.70	Panadol	GC
5344G NP	paracetamol 665 mg tablet: modified release, 96 tablets	2	..	..	*15.34	16.49	^a Osteomol 665	CR
				^B 1.64	*16.98	16.49	^a Paracetamol Panadol Osteo	GC

ANTIEPILEPTICS

ANTIEPILEPTICS

Benzodiazepine derivatives

CLONAZEPAM

Authority required

Initial supply, for up to 4 months, for a palliative care patient for the prevention of epilepsy

Note

No applications for increased repeats will be authorised.

5338Y NP	clonazepam 2 mg tablet, 100	1	3	..	19.08	20.23	^a Paxam 2	AF
				^B 1.93	21.01	20.23	^a Rivotril	RO
5339B NP	clonazepam 2.5 mg/mL oral liquid, 10 mL	2	3	..	*15.38	16.53	Rivotril	RO
5337X NP	clonazepam 500 microgram tablet, 100	1	3	..	13.30	14.45	^a Paxam 0.5	AF
				^B 1.71	15.01	14.45	^a Rivotril	RO

CLONAZEPAM

Authority required

Continuing supply for a palliative care patient for the prevention of epilepsy

Note

Where consultation with a palliative care specialist or service has occurred, applications for increased repeats may be authorised.

5341D NP	clonazepam 2 mg tablet, 100	1	..	..	19.08	20.23	^a Paxam 2	AF
				^B 1.93	21.01	20.23	^a Rivotril	RO
5342E NP	clonazepam 2.5 mg/mL oral liquid, 10 mL	2	..	..	*15.38	16.53	Rivotril	RO
5340C NP	clonazepam 500 microgram tablet, 100	1	..	..	13.30	14.45	^a Paxam 0.5	AF
				^B 1.71	15.01	14.45	^a Rivotril	RO

PSYCHOLEPTICS

ANXIOLYTICS

Benzodiazepine derivatives

DIAZEPAM

Authority required

Initial supply, for up to 4 months, for a palliative care patient where anxiety is a problem

Note

No applications for increased repeats will be authorised.

5355W NP	diazepam 2 mg tablet, 50	1	3	..	7.92	9.07	^a Antenex 2	AF
							^a APO-Diazepam	TX
							^a Ranzepam	RA
							^a Valpam 2	QA
5356X NP	diazepam 5 mg tablet, 50	1	3	..	8.04	9.19	^a Antenex 5	AF
							^a APO-Diazepam	TX
							^a Ranzepam	RA
							^a Valpam 5	QA
				^B 2.52	10.56	9.19	^a Valium	RO

DIAZEPAM

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
Authority required								
Continuing supply for a palliative care patient where anxiety is a problem								
Note								
Where consultation with a palliative care specialist or service has occurred, applications for increased repeats may be authorised.								
5357Y NP	diazepam 2 mg tablet, 50	1	..	..	7.92	9.07	^a Antenex 2	AF
							^a APO-Diazepam	TX
							^a Ranzepam	RA
							^a Valpam 2	QA
5358B NP	diazepam 5 mg tablet, 50	1	..	..	8.04	9.19	^a Antenex 5	AF
							^a APO-Diazepam	TX
							^a Ranzepam	RA
							^a Valpam 5	QA
				^B 2.52	10.56	9.19	^a Valium	RO

OXAZEPAM

Authority required

Initial supply, for up to 4 months, for a palliative care patient where anxiety is a problem

Note

No applications for increased repeats will be authorised.

5371Q NP	oxazepam 15 mg tablet, 25	2	3	..	*9.24	10.39	^a Alepam 15	AF
				^B 5.36	*14.60	10.39	^a Serepax	QA
5372R NP	oxazepam 30 mg tablet, 25	2	3	..	*9.24	10.39	^a Alepam 30	AF
							^a APO-Oxazepam	TX
							^a Murelax	FM
				^B 5.36	*14.60	10.39	^a Serepax	QA

OXAZEPAM

Authority required

Continuing supply for a palliative care patient where anxiety is a problem

Note

Where consultation with a palliative care specialist or service has occurred, applications for increased repeats may be authorised.

5373T NP	oxazepam 15 mg tablet, 25	2	..	..	*9.24	10.39	^a Alepam 15	AF
				^B 5.36	*14.60	10.39	^a Serepax	QA
5374W NP	oxazepam 30 mg tablet, 25	2	..	..	*9.24	10.39	^a Alepam 30	AF
							^a APO-Oxazepam	TX
							^a Murelax	FM
				^B 5.36	*14.60	10.39	^a Serepax	QA

HYPNOTICS AND SEDATIVES

Benzodiazepine derivatives

NITRAZEPAM

Authority required

Initial supply, for up to 4 months, for a palliative care patient where insomnia is a problem

Note

No applications for increased repeats will be authorised.

5359C NP	nitrazepam 5 mg tablet, 25	2	3	..	*9.94	11.09	^a Alodorm	AF
				^B 2.48	*12.42	11.09	^a Mogadon	IA

NITRAZEPAM

Authority required

Continuing supply for a palliative care patient where insomnia is a problem

Note

Where consultation with a palliative care specialist or service has occurred, applications for increased repeats may be authorised.

5360D	nitrazepam 5 mg tablet, 25	2	..	..	*9.94	11.09	^a Alodorm	AF

PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
NP				^B 2.48	*12.42	11.09	^a Mogadon	IA
TEMAZEPAM								
<u>Authority required</u>								
Initial supply, for up to 4 months, for a palliative care patient where insomnia is a problem								
<u>Note</u>								
No applications for increased repeats will be authorised.								
5375X NP	temazepam 10 mg tablet, 25	2	3	..	*8.62	9.77	^a APO-Temazepam	TX
							^a Temaze	AF
							^a Temtabs	FM
				^B 8.00	*16.62	9.77	^a Normison	QA
TEMAZEPAM								
<u>Authority required</u>								
Continuing supply for a palliative care patient where insomnia is a problem								
<u>Note</u>								
Where consultation with a palliative care specialist or service has occurred, applications for increased repeats may be authorised.								
5376Y NP	temazepam 10 mg tablet, 25	2	..	..	*8.62	9.77	^a APO-Temazepam	TX
							^a Temaze	AF
							^a Temtabs	FM
				^B 8.00	*16.62	9.77	^a Normison	QA

Items Available under Special Arrangements(Section 100)

Section 100 – Items Available under Special Arrangement

In addition to the drugs and medicinal preparations available under normal PBS arrangements listed in this Schedule, a number of drugs are also available as pharmaceutical benefits but are distributed under alternative arrangements where these are considered more appropriate.

These alternative arrangements are provided for under section 100 of the National Health Act 1953. Several programs exist for the provision of drugs as pharmaceutical benefits in this way and this section lists those drugs which are available under the following programs:

- **Highly Specialised Drugs Program**
- **Botulinum Toxin Program**
- **Human Growth Hormone Program**
- **IVF/GIFT Program**
- **Opiate Dependence Treatment Program**

Complete details concerning the availability of drugs as benefits under these programs may be obtained by telephoning the relevant contact number(s) shown in each section, or in certain cases, by referring to the telephone number provided for individual drugs listings.

Section 100 – Highly Specialised Drugs Program

The Australian Government provides funding for certain specialised medications under the Highly Specialised Drugs Program. Highly Specialised Drugs are medicines for the treatment of chronic conditions which, because of their clinical use or other special features, are restricted to supply through public and private hospitals having access to appropriate specialist facilities. To prescribe these drugs as pharmaceutical benefit items, medical practitioners are required to be affiliated with these specialist hospital units. A general practitioner or non-specialist hospital doctor may only prescribe Highly Specialised Drugs to provide maintenance therapy under the guidance of the treating specialist.

Benefits are available for the listed clinical indications only. There is no facility for individual patient approval for indications outside those listed.

To gain access to a Commonwealth funded drug under this program, a patient must attend a participating hospital and be a day admitted patient, a non-admitted patient or a patient on discharge, be under appropriate specialist medical care, meet the specific medical criteria and be an Australian resident in Australia (or other eligible person).

A patient will be required to pay a contribution for each supply of a highly specialised drug at a similar rate to the Pharmaceutical Benefits Scheme. Commonwealth subsidy is not available for hospital in-patients.

Reciprocal Health Care Agreement – Where a patient is entitled to be treated as an eligible person as a visitor from a country with which Australia has entered into a Reciprocal Health Care Agreement, the supply will be limited to the original prescription only. Repeat prescriptions for these patients are not permitted.

Private Hospitals – **In addition to the above requirements**, for Highly Specialised Drugs prescribed through private hospitals, claiming and approval of authority prescriptions is administered by Medicare Australia. Highly Specialised Drugs are authority required items. Medical practitioners must seek approval to prescribe these items as pharmaceutical benefits prior to their dispensing under the PBS. Approval of authority prescriptions by Medicare Australia may be obtained either by posting an Authority Prescription Form to Medicare Australia, or by using Medicare Australia's Authority Freecall service (1800 888 333). **Prescribers must quote the provider number of the hospital when applying.** Not more than two months' supply (one month's supply in the case of Clozapine), with provision for up to 5 repeats, will be authorised. Prescriptions for Highly Specialised Drugs can be dispensed by an approved private hospital's dispensary or by a community pharmacy.

The remuneration rates for Highly Specialised Drugs prescribed through private hospitals comprise the normal PBS ready- prepared dispensing fee plus a mark-up ascertained as follows:

- 10% for drugs with a price ex-manufacturer of less than \$40;
- \$4 for drugs with a price ex-manufacturer of between \$40 and \$100;
- 4% for drugs with a price ex-manufacturer of between \$100.01 and \$1000;
- \$40 for drugs with a price ex-manufacturer of greater than \$1000.

Public Hospitals – For Highly Specialised Drugs prescribed through public hospitals, claiming and access to the program is administered by the States/Territories Health Departments. Prescriptions for Highly Specialised Drugs can be dispensed by public hospital pharmacies.

If you would like further information about the Highly Specialised Drugs Program, please contact your pharmacy, Medicare Australia (Ph: 132 290) or the Australian Government adviser, the Highly Specialised Drugs Working Party Secretariat (Ph: (02) 6289 2331).

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

BLOOD AND BLOOD FORMING ORGANS

ANTIHEMORRHAGICS

VITAMIN K AND OTHER HEMOSTATICS

Other systemic hemostatics

ELTROMBOPAG

Authority required

Initial (new patients)

Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who is:

(1) Splenectomised and:

(a) has had an inadequate response to, or is intolerant to, corticosteroid therapy post splenectomy; and

(b) has had an inadequate response to, or is intolerant to, immunoglobulin therapy post splenectomy;

OR

(2) Not splenectomised and:

(a) has had an inadequate response, or is intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks; and

(b) has had an inadequate response, or is intolerant to, immunoglobulin therapy; and

(c) in whom splenectomy is contraindicated for medical reasons.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of initial application:

(a) a platelet count of less than or equal to 20,000 million per L;

OR

(b) a platelet count of 20-30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made in writing and must include:

(1) a completed authority prescription form,

(2) a signed patient acknowledgement,

(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)],

(4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and

(5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion

Authority required

Initial (grandfather patients)

Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with eltrombopag prior to 1 November 2011 and in whom the criteria for initial treatment can be demonstrated to have been met at the time eltrombopag was commenced.

The authority application must be made in writing and must include:

(1) a completed authority prescription form,

(2) a signed patient acknowledgement,

(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and

(4) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion

Authority required

Continuing therapy or re-initiation after a break in therapy

First period of PBS-subsidised continuing treatment or re-initiation of interrupted PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has displayed a sustained platelet response to treatment with eltrombopag during the initial period of PBS-subsidised treatment.

For the purposes of this restriction, a sustained platelet response is defined as:

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer	
					Price for Max. Qty \$		
	(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised eltrombopag, AND either of the following: (b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart; OR (c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart. Applications for the first period of continuing PBS-subsidised treatment or re-initiation of interrupted treatment must be made in writing and must include: (1) a completed authority prescription form, and (2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and (3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy). The most recent platelet count must be no more than one month old at the time of application. A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion. Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be made by telephone Authority required Second and subsequent applications for continuing therapy Continuing treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has previously received PBS-subsidised therapy with eltrombopag and who continues to display a response to treatment with eltrombopag. For the purposes of this restriction, a continuing response to treatment with eltrombopag is defined as: (a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with eltrombopag, AND either of the following: (b) a platelet count greater than or equal to 50,000 million per L OR (c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count. Platelet counts must be no more than 1 month old at the time of application. Authority applications for second and subsequent periods of continuing therapy may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) Note Eltrombopag is not PBS-subsidised as an alternative to splenectomy. Any queries concerning the arrangements to prescribe eltrombopag may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written applications for authority to prescribe eltrombopag should be forwarded to: Medicare Australia Prior Written Approval of Specialised Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au. Note Patients will be able to trial either eltrombopag and/or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with either eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs. No applications for increased repeats will be authorised. Note No applications for increased repeats will be authorised.						
5827Q	eltrombopag 25 mg tablet, 28	1	5	..	1558.76	Revolade	GK
5828R	eltrombopag 50 mg tablet, 28	1	5	..	3070.76	Revolade	GK

ROMIPLOSTIM

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

Authority required

Initial (new patients)

Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who is:

(1) Splenectomised and:

(a) has had an inadequate response to, or is intolerant to, corticosteroid therapy post splenectomy; and

(b) has had an inadequate response to, or is intolerant to, immunoglobulin therapy post splenectomy;

OR

(2) Not splenectomised and:

(a) has had an inadequate response, or is intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks; and

(b) has had an inadequate response, or is intolerant to, immunoglobulin therapy; and

(c) in whom splenectomy is contraindicated for medical reasons.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of initial application:

(a) a platelet count of less than or equal to 20,000 million per L;

OR

(b) a platelet count of 20-30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made in writing and must include:

(1) a completed authority prescription form,

(2) a signed patient acknowledgement,

(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)],

(4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and

(5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

At the time of the written authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The dose (microgram/kg/week) must be provided at the time of application.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week

Authority required

Initial (grandfather patients)

Initial PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with romiplostim prior to 1 April 2011 and in whom the criteria for initial treatment can be demonstrated to have been met at the time romiplostim was commenced.

The authority application must be made in writing and must include:

(1) a completed authority prescription form,

(2) a signed patient acknowledgement,

(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and

(4) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

For patients whose dose of romiplostim had been stable for at least 4 weeks at the time of the initial application for PBS-subsidy, the medical practitioner should request sufficient number of vials based on the weight of the patient and dose (microgram/kg/week) to provide up to 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Where the patient is in the titration phase of treatment with romiplostim, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The dose (microgram/kg/week) must be provided at the time of application.

Note

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer	
	HOBART TAS 7001						
	Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au .						
	<u>Note</u>						
	Patients will be able to trial either eltrombopag and/or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with either eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.						
	<u>Note</u>						
	Special Pricing Arrangements apply.						
9697J	romiplostim 250 microgram injection, 1 x 250 microgram vial	1	..	..	1023.36	Nplate	AN
9699L	romiplostim 500 microgram injection, 1 x 500 microgram vial	1	..	..	2001.76	Nplate	AN

ANTIANEMIC PREPARATIONS

OTHER ANTIANEMIC PREPARATIONS

Other antianemic preparations

DARBEPOETIN ALFA

Authority required

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia

6320P	darbepoetin alfa 10 microgram/0.4 mL injection, 4 x 0.4 mL syringes	2	5	..	*377.08	Aranesp	AN
6492Q	darbepoetin alfa 100 microgram/0.5 mL injection, 1 x 0.5 mL syringe	8	5	..	*2667.24	Aranesp SureClick	AN
6326Y	darbepoetin alfa 100 microgram/0.5 mL injection, 4 x 0.5 mL syringes	2	5	..	*2667.26	Aranesp	AN
6493R	darbepoetin alfa 150 microgram/0.3 mL injection, 1 x 0.3 mL syringe	8	5	..	*3951.24	Aranesp SureClick	AN
6365B	darbepoetin alfa 150 microgram/0.3 mL injection, 4 x 0.3 mL syringes	2	5	..	*3951.26	Aranesp	AN
6488L	darbepoetin alfa 20 microgram/0.5 mL injection, 1 x 0.5 mL syringe	8	5	..	*704.20	Aranesp SureClick	AN
6321Q	darbepoetin alfa 20 microgram/0.5 mL injection, 4 x 0.5 mL syringes	2	5	..	*704.20	Aranesp	AN
6322R	darbepoetin alfa 30 microgram/0.3 mL injection, 4 x 0.3 mL syringes	2	5	..	*960.92	Aranesp	AN
6489M	darbepoetin alfa 40 microgram/0.4 mL injection, 1 x 0.4 mL syringe	8	5	..	*1160.36	Aranesp SureClick	AN
6323T	darbepoetin alfa 40 microgram/0.4 mL injection, 4 x 0.4 mL syringes	2	5	..	*1160.36	Aranesp	AN
6324W	darbepoetin alfa 50 microgram/0.5 mL injection, 4 x 0.5 mL syringes	2	5	..	*1423.54	Aranesp	AN
6490N	darbepoetin alfa 60 microgram/0.3 mL injection, 1 x 0.3 mL syringe	8	5	..	*1663.40	Aranesp SureClick	AN
6325X	darbepoetin alfa 60 microgram/0.3 mL injection, 4 x 0.3 mL syringes	2	5	..	*1663.42	Aranesp	AN
6491P	darbepoetin alfa 80 microgram/0.4 mL injection, 1 x 0.4 mL syringe	8	5	..	*2174.76	Aranesp SureClick	AN
6438W	darbepoetin alfa 80 microgram/0.4 mL injection, 4 x 0.4 mL syringes	2	5	..	*2174.76	Aranesp	AN

EPOETIN ALFA

Authority required

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia

6207Q	epoetin alfa 10 000 international units/mL injection, 6 x 1 mL syringes	2	5	..	*2017.06	Eprex 10000	JC
6251B	epoetin alfa 1000 international units/0.5 mL injection, 6 x 0.5 mL syringes	2	5	..	*297.24	Eprex 1000	JC
6434P	epoetin alfa 20 000 international units/0.5 mL injection, 6 x 0.5 mL syringes	2	5	..	*3922.76	Eprex 20,000	JC

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty	Brand Name and Manufacturer	
					\$		
6204M	epoetin alfa 2000 international units/0.5 mL injection, 6 x 0.5 mL syringes	2	5	..	*544.24	Eprex 2000	JC
6205N	epoetin alfa 3000 international units/0.3 mL injection, 6 x 0.3 mL syringes	2	5	..	*700.34	Eprex 3000	JC
6339P	epoetin alfa 40 000 international units/mL injection, 1 x 1 mL syringe	2	5	..	*1300.76	Eprex 40,000	JC
6206P	epoetin alfa 4000 international units/0.4 mL injection, 6 x 0.4 mL syringes	2	5	..	*890.04	Eprex 4000	JC
6302Q	epoetin alfa 5000 international units/0.5 mL injection, 6 x 0.5 mL syringes	2	5	..	*1104.10	Eprex 5000	JC
6303R	epoetin alfa 6000 international units/0.6 mL injection, 6 x 0.6 mL syringes	2	5	..	*1301.90	Eprex 6000	JC
6305W	epoetin alfa 8000 international units/0.8 mL injection, 6 x 0.8 mL syringes	2	5	..	*1674.68	Eprex 8000	JC

EPOETIN BETA

Authority required

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia

6485H	epoetin beta 10 000 international units/0.6 mL injection, 6 x 0.6 mL syringes	2	5	..	*2017.06	NeoRecormon	RO
6480C	epoetin beta 2000 international units/0.3 mL injection, 6 x 0.3 mL syringes	2	5	..	*544.24	NeoRecormon	RO
6481D	epoetin beta 3000 international units/0.3 mL injection, 6 x 0.3 mL syringes	2	5	..	*700.34	NeoRecormon	RO
6482E	epoetin beta 4000 international units/0.3 mL injection, 6 x 0.3 mL syringes	2	5	..	*890.04	NeoRecormon	RO
6483F	epoetin beta 5000 international units/0.3 mL injection, 6 x 0.3 mL syringes	2	5	..	*1104.12	NeoRecormon	RO
6484G	epoetin beta 6000 international units/0.3 mL injection, 6 x 0.3 mL syringes	2	5	..	*1301.90	NeoRecormon	RO

EPOETIN LAMBDA

Authority required

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia

Note

Epoetin lambda should only be administered by the intravenous route.

9595B	epoetin lambda 10 000 international units/mL injection, 6 x 1 mL syringes	2	5	..	*1913.36	Novicrit	SZ
9685R	epoetin lambda 1000 international units/0.5 mL injection, 6 x 0.5 mL syringes	2	5	..	*281.94	Novicrit	SZ
9686T	epoetin lambda 2000 international units/mL injection, 6 x 1 mL syringes	2	5	..	*515.94	Novicrit	SZ
9687W	epoetin lambda 3000 international units/0.3 mL injection, 6 x 0.3 mL syringes	2	5	..	*663.84	Novicrit	SZ
9688X	epoetin lambda 4000 international units/0.4 mL injection, 6 x 0.4 mL syringes	2	5	..	*843.54	Novicrit	SZ
9588P	epoetin lambda 5000 international units/0.5 mL injection, 6 x 0.5 mL syringes	2	5	..	*1048.46	Novicrit	SZ
9590R	epoetin lambda 6000 international units/0.6 mL injection, 6 x 0.6 mL syringes	2	5	..	*1235.84	Novicrit	SZ
9593X	epoetin lambda 8000 international units/0.8 mL injection, 6 x 0.8 mL syringes	2	5	..	*1589.00	Novicrit	SZ

METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA

Authority required

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia

9577C	methoxy polyethylene glycol-epoetin beta 100 microgram/0.3 mL injection, 1 x 0.3 mL syringe	2	5	..	*1205.58	Mircera	RO
9578D	methoxy polyethylene glycol-epoetin beta 120 microgram/0.3 mL injection, 1 x 0.3 mL syringe	2	5	..	*1388.40	Mircera	RO

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty	Brand Name and Manufacturer	
					\$		
9579E	methoxy polyethylene glycol-epoetin beta 200 microgram/0.3 mL injection, 1 x 0.3 mL syringe	2	5	..	*1971.06	Mircera	RO
9574X	methoxy polyethylene glycol-epoetin beta 30 microgram/0.3 mL injection, 1 x 0.3 mL syringe	2	5	..	*390.70	Mircera	RO
9580F	methoxy polyethylene glycol-epoetin beta 360 microgram/0.6 mL injection, 1 x 0.6 mL syringe	2	5	..	*3373.28	Mircera	RO
9575Y	methoxy polyethylene glycol-epoetin beta 50 microgram/0.3 mL injection, 1 x 0.3 mL syringe	2	5	..	*646.68	Mircera	RO
9576B	methoxy polyethylene glycol-epoetin beta 75 microgram/0.3 mL injection, 1 x 0.3 mL syringe	2	5	..	*938.62	Mircera	RO

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
				\$	\$	\$	

CARDIOVASCULAR SYSTEM

ANTIHYPERTENSIVES

OTHER ANTIHYPERTENSIVES

Other antihypertensives

AMBRISANTAN

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease,

AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds,

AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	

conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH; OR

Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease,

AND

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgement. Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. Test requirements to establish baseline for initiation of treatment are as follows: The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements. Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats may be requested. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan. Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.					

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
- (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note

Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	

GPO Box 9826

HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition,

AND

The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

Note

Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (all patients)

Clinical criteria:

Patient must have received approval for initial PBS-subsidised treatment with this agent,

AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer	
(6) ECHO composite assessment only. The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application. Response to a PAH agent is defined as follows: For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats will be authorised. The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician. Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy. Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.							
9649W	ambrisentan 10 mg tablet, 30	1	..	..	2923.23	Volibris	GK
9648T	ambrisentan 5 mg tablet, 30	1	..	..	2923.23	Volibris	GK

BOSENTAN

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	AND					
	Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH; OR					
	Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease,					
	AND					
	Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR					
	Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds,					
	AND					
	Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists,					
	AND					
	The treatment must be the sole PBS-subsidised PAH agent for this condition.					
	Applications for authorisation must be in writing and must include:					
	(1) two completed authority prescription forms; and					
	(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:					
	(i) RHC composite assessment; and					
	(ii) ECHO composite assessment; and					
	(iii) 6 Minute Walk Test (6MWT); and					
	(3) a signed patient acknowledgement.					
	Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:					
	(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or					
	(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.					
	Test requirements to establish baseline for initiation of treatment are as follows:					
	The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.					
	Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:					
	(1) RHC plus ECHO composite assessments;					
	(2) RHC composite assessment plus 6MWT;					
	(3) RHC composite assessment only.					
	In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:					
	(1) ECHO composite assessment plus 6MWT;					
	(2) ECHO composite assessment only.					
	Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.					
	The test results provided must not be more than 2 months old at the time of application.					
	Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.					
	Response to prior vasodilator treatment is defined as follows:					
	For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.					
	For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.					
	For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.					
	For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.					
	Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved					

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for this prescription. The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. Note Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient. Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals. Authority required Pulmonary arterial hypertension (PAH) Treatment Phase: Initial 2 (new patients) Clinical criteria: Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND Patient must have been assessed by a physician at a designated hospital, AND Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH; OR Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include: (1) two completed authority prescription forms; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	

- (i) RHC composite assessment; and
- (ii) ECHO composite assessment; and
- (iii) 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) two completed authority prescription forms; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
- (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note

Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty	\$	
	Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.						

Note

Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition,

AND

The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

Note

Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services

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Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (all patients)

Clinical criteria:

Patient must have received approval for initial PBS-subsidised treatment with this agent,

AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					Price for Max.	Qty	
					\$	\$	

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
- (i) RHC composite assessment; and
- (ii) ECHO composite assessment; and
- (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Caution

This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

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HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer	
					Price for Max. Qty \$		
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.							
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BOSENTAN

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease,

AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds,

AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) two completed authority prescription forms; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.					
	Response to prior vasodilator treatment is defined as follows:					
	For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.					
	For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.					
	For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.					
	For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.					
	Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for this prescription.					
	The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.					
	Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.					
	The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.					
	PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.					
	Note					
	Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.					
	The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.					
	Note					
	Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).					
	Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au					
	Applications for authority to prescribe should be forwarded to:					
	Department of Human Services					
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	GPO Box 9826					
	HOBART TAS 7001					
	Note					
	Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.					
	Authority required					
	Pulmonary arterial hypertension (PAH)					
	Treatment Phase: Initial 2 (new patients)					
	Clinical criteria:					
	Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,					
	AND					
	Patient must have been assessed by a physician at a designated hospital,					
	AND					
	Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR					
	Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR					
	Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR					
	Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

assessed by ECHO where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH; OR

Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR

Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology),

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) two completed authority prescription forms; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) two completed authority prescription forms; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
- (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					Qty	\$	

patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note

Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

Note

Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition,

AND

The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

Note

Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (all patients)

Clinical criteria:

Patient must have received approval for initial PBS-subsidised treatment with this agent,

AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer	
					Qty \$			
	Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 <u>Note</u> Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals. <u>Authority required</u> Pulmonary arterial hypertension (PAH) Treatment Phase: Cessation of treatment (all patients) Clinical criteria: Patient must have received approval for initial PBS-subsidised treatment with this agent, AND Patient must have not responded to prior PBS-subsidised therapy with this agent, AND The treatment must be for the purpose of gradual dose reduction prior to ceasing therapy, AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment. Treatment beyond 1 month will not be approved. <u>Caution</u> This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy. <u>Note</u> Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written applications for authorisation under this criterion should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001							
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HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.	Brand Name and Manufacturer
					Qty \$	

- (i) RHC composite assessment; and
- (ii) ECHO composite assessment; and
- (iii) 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note

Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 1.5 mg (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 1.5 mg injection vial are equivalent for the purposes of substitution.

Note

Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 500 micrograms (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 500 microgram injection vial are equivalent for the purposes of substitution.

Authority required

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty	\$	

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change or re-commencement of therapy for all patients)

Clinical criteria:

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and must have received prior treatment with a PBS-subsidised PAH agent other than this agent; OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and must have failed to respond to a prior PBS-subsidised PAH agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
- (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and
- (4) for WHO Functional Class III patients, where this is the first application for this agent, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note

Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001					
	Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.					
	Note Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 1.5 mg (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 1.5 mg injection vial are equivalent for the purposes of substitution.					
	Note Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 500 micrograms (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 500 microgram injection vial are equivalent for the purposes of substitution.					
	Authority required Pulmonary arterial hypertension (PAH) Treatment Phase: Initial 1 (new patients) or Initial 2 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply					
	Clinical criteria: Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the Initial 2 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment,					
	AND The treatment must be the sole PBS-subsidised PAH agent for this condition,					
	AND The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.					
	Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written applications for authorisation under this criterion should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001					
	Note Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 1.5 mg (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 1.5 mg injection vial are equivalent for the purposes of substitution.					
	Note Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 500 micrograms (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 500 microgram injection vial are equivalent for the purposes of substitution.					
	Authority required Pulmonary arterial hypertension (PAH) Treatment Phase: Continuing treatment (all patients)					
	Clinical criteria: Patient must have received approval for initial PBS-subsidised treatment with this agent,					
	AND Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent,					
	AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include:					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.	Brand Name and Manufacturer
					Qty \$	

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
- (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note

Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 1.5 mg (base) infusion administration set and

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer	
					Qty \$			
pharmaceutical benefits that have the form epoprostenol 1.5 mg injection vial are equivalent for the purposes of substitution.								
<u>Note</u>								
Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 500 micrograms (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 500 microgram injection vial are equivalent for the purposes of substitution.								
5042J	EPOPROSTENOL SODIUM Powder for I.V. infusion 1.5 mg (base) infusion administration set, 1	1	..	..	77.31	^a	Flolan Kit	GK
5036C	EPOPROSTENOL SODIUM Powder for I.V. infusion 500 micrograms (base) infusion administration set, 1	1	..	..	43.37	^a	Flolan Kit	GK
10129D	epoprostenol 1.5 mg injection, 1 x 1.5 mg vial	1	..	..	77.31	^a	Veletri	AT
10111E	epoprostenol 500 microgram injection, 1 x 500 microgram vial	1	..	..	43.37	^a	Veletri	AT

ILOPROST

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with this agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III drug-induced PAH,

AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds,

AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					Price for Max.	Qty	
					\$	\$	

following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note

Special Pricing Arrangements apply.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III drug-induced PAH and a mean right atrial pressure greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III drug-induced PAH with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH; OR

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR					
	Patient must have WHO Functional Class IV drug-induced PAH,					
	AND					
	The treatment must be the sole PBS-subsidised PAH agent for this condition.					
	Applications for authorisation must be in writing and must include:					
	(1) a completed authority prescription form; and					
	(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:					
	(i) RHC composite assessment; and					
	(ii) ECHO composite assessment; and					
	(iii) 6 Minute Walk Test (6MWT); and					
	(3) a signed patient acknowledgement.					
	Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:					
	(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or					
	(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.					
	Test requirements to establish baseline for initiation of treatment are as follows:					
	The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.					
	Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:					
	(1) RHC plus ECHO composite assessments;					
	(2) RHC composite assessment plus 6MWT;					
	(3) RHC composite assessment only.					
	In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:					
	(1) ECHO composite assessment plus 6MWT;					
	(2) ECHO composite assessment only.					
	Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.					
	The test results provided must not be more than 2 months old at the time of application.					
	The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.					
	A maximum of 5 repeats may be requested.					
	The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.					
	Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.					
	PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.					
	Note					
	Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).					
	Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au					
	Applications for authority to prescribe should be forwarded to:					
	Department of Human Services					
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	GPO Box 9826					
	HOBART TAS 7001					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note

Special Pricing Arrangements apply.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease or drug-induced PAH and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and must have received prior treatment with a PBS-subsidised PAH agent other than this agent; OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and must have failed to respond to a prior PBS-subsidised PAH agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
- (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and
- (4) for WHO Functional Class III patients, where this is the first application for this agent, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note

Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	
	<u>Note</u> Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001					
	<u>Note</u> Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.					
	<u>Note</u> Special Pricing Arrangements apply.					
	<u>Authority required</u> Pulmonary arterial hypertension (PAH) Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply					
	Clinical criteria: Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment,					
	AND The treatment must be the sole PBS-subsidised PAH agent for this condition,					
	AND The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.					
	<u>Note</u> Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written applications for authorisation under this criterion should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001					
	<u>Note</u> Special Pricing Arrangements apply.					
	<u>Authority required</u> Pulmonary arterial hypertension (PAH) Treatment Phase: Continuing treatment (all patients)					
	Clinical criteria: Patient must have received approval for initial PBS-subsidised treatment with this agent,					
	AND Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent,					
	AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include:					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.	Brand Name and Manufacturer
					Qty \$	

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
- (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note

Special Pricing Arrangements apply.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer	
					Price for Max. Qty \$		
6456T	iloprost 20 microgram/2 mL inhalation: solution, 30 x 2 mL ampoules	1	..	..	1122.76	Ventavis	BN

MACITENTAN

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease,

AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds,

AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH; OR

Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR

Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology),

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	(1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgement. Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. Test requirements to establish baseline for initiation of treatment are as follows: The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements. Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats may be requested. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan. Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals. Authority required Pulmonary arterial hypertension (PAH) Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients) Clinical criteria:					

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application. Response to a PAH agent is defined as follows: For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats may be requested. Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing. Note Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing. Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
	HOBART TAS 7001						

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition,

AND

The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

Note

Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (all patients)

Clinical criteria:

Patient must have received approval for initial PBS-subsidised treatment with this agent,

AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer	
					Qty \$			
	The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application. Response to a PAH agent is defined as follows: For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats will be authorised. The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician. Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy. Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.							
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Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease,

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	AND Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, AND Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgement. Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. Test requirements to establish baseline for initiation of treatment are as follows: The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements. Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application. Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application. Response to prior vasodilator treatment is defined as follows: For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty	\$	

PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty	\$	

order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
- (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note

Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition,

AND

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

Note

Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (all patients)

Clinical criteria:

Patient must have received approval for initial PBS-subsidised treatment with this agent,

AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					Qty	\$	

continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

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Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

9605M	sildenafil 20 mg tablet, 90	1	..	..	791.63	^a	APO-Sildenafil PHT	TX
						^a	Revatio	PF
						^a	Sildenafil AN PHT 20	EA
						^a	SILDENAFIL-DRx	RZ
						^a	Sildenafil Sandoz PHT 20	SZ

TADALAFIL

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease,

AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds,

AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension,

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. Test requirements to establish baseline for initiation of treatment are as follows: The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements. Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application. Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application. Response to prior vasodilator treatment is defined as follows: For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					Price for Max.	Qty	
					\$	\$	

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	
	PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.					

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
- (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty	\$	

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note

Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

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HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition,

AND

The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

Note

Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (all patients)

Clinical criteria:

Patient must have received approval for initial PBS-subsidised treatment with this agent,

AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent,

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

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Prior Written Approval of Complex Drugs

Reply Paid 9826

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HOBART TAS 7001

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					Qty \$		
Note							
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.							
1304P	tadalafil 20 mg tablet, 56	1	..	..	878.83	Adcirca	LY

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	

SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

HYPOTHALAMIC HORMONES

Somatostatin and analogues

LANREOTIDE

Authority required

Acromegaly

Clinical criteria:

The condition must be active,

AND

Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre,

AND

The treatment must be after failure of other therapy including dopamine agonists; OR

The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR

The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated,

AND

The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose),

AND

The treatment must cease if IGF1 is not lower after 3 months of treatment.

In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

Authority required

Functional carcinoid tumour

Clinical criteria:

The condition must be causing intractable symptoms,

AND

Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents,

AND

Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate,

AND

The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

6425E	lanreotide 120 mg injection, 1 syringe	2	5	..	*4526.76	Somatuline Autogel	IS
6423C	lanreotide 60 mg injection, 1 syringe	2	5	..	*2736.76	Somatuline Autogel	IS
6424D	lanreotide 90 mg injection, 1 syringe	2	5	..	*3626.76	Somatuline Autogel	IS

LANREOTIDE

Authority required

Acromegaly

Clinical criteria:

The condition must be active,

AND

Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre,

AND

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer	
					Price for Max. Qty \$		
6332G	The treatment must be after failure of other therapy including dopamine agonists; OR						
	The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR						
	The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated,						
	AND						
	The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (6 weeks after the last dose),						
	AND						
	The treatment must cease if IGF1 is not lower after 3 months of treatment.						
	In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.						
	lanreotide 30 mg injection: modified release [1 x 30 mg vial] (&) inert substance diluent [1 x 2 mL ampoule], 1 pack	2	11	..	*1546.76	Somatuline LA	IS
	OCTREOTIDE						
<u>Authority required</u>							
Acromegaly							
Clinical criteria:							
The condition must be controlled with octreotide immediate release injections,							
AND							
The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose),							
AND							
The treatment must cease if IGF1 is not lower after 3 months of treatment.							
In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission							
<u>Authority required</u>							
Functional carcinoid tumour							
Clinical criteria:							
Patient must have achieved symptom control on octreotide immediate release injections,							
AND							
The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.							
Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.							
<u>Authority required</u>							
Vasoactive intestinal peptide secreting tumour (VIPoma)							
Clinical criteria:							
Patient must have achieved symptom control on octreotide immediate release injections,							
AND							
The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.							
Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.							
6426F	octreotide 10 mg injection: modified release [1 x 10 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack	2	5	..	*2660.48	Sandostatin LAR	NV
6427G	octreotide 20 mg injection: modified release [1 x 20 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack	2	5	..	*3526.38	Sandostatin LAR	NV
6428H	octreotide 30 mg injection: modified release [1 x 30 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack	2	5	..	*4401.68	Sandostatin LAR	NV

OCTREOTIDE

Authority required

Active acromegaly in a patient with persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre AND

(a) after failure of other therapy including dopamine agonists; or

(b) as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or

(c) if the patient is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer	
					Qty \$			
In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks. Octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission. Treatment must cease if IGF1 is not lower after 3 months treatment at a dose of 100 micrograms 3 times daily Authority required Functional carcinoid tumour or vasoactive intestinal peptide secreting tumour (VIPoma) causing intractable symptoms. The patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, and surgery or antineoplastic therapy must have failed or be inappropriate. Treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose								
6228T	octreotide 100 microgram/mL injection, 5 x 1 mL ampoules	18	11	..	*1283.14	^a	Hospira Pty Limited	HH
						^a	Octreotide (SUN)	ZF
						^a	Octreotide MaxRx	GQ
						^a	Sandostatin 0.1	NV
6227R	octreotide 50 microgram/mL injection, 5 x 1 mL ampoules	18	11	..	*650.62	^a	Hospira Pty Limited	HH
						^a	Octreotide (SUN)	ZF
						^a	Octreotide MaxRx	GQ
						^a	Sandostatin 0.05	NV
6229W	octreotide 500 microgram/mL injection, 5 x 1 mL ampoules	18	11	..	*6241.24	^a	Hospira Pty Limited	HH
						^a	Octreotide (SUN)	ZF
						^a	Octreotide MaxRx	GQ
						^a	Sandostatin 0.5	NV

CALCIUM HOMEOSTASIS

ANTI-PARATHYROID AGENTS

Other anti-parathyroid agents

CINACALCET

Authority required

Management, including initiation and stabilisation, by a nephrologist, of a patient with chronic kidney disease on dialysis who has sustained secondary hyperparathyroidism with iPTH of at least 50 pmol per L, not responding to conventional therapy

Authority required

Management, including initiation and stabilisation, by a nephrologist, of a patient with chronic kidney disease on dialysis who has sustained secondary hyperparathyroidism with iPTH of at least 15 pmol per L and less than 50 pmol per L AND an (adjusted) serum calcium concentration at least 2.6 mmol per L, not responding to conventional treatment

Note

During the titration phase, intact PTH should be monitored 4 weekly (measured at least 12 hours post dose) and dose titrated until an appropriate iPTH concentration is achieved. During the titration phase, approval will be limited to sufficient supply for 4 weeks treatment at a time, with doses between 30 and 180 mg per day according to the patient's response and tolerability.

During the maintenance phase, approval will be limited to provide sufficient quantity for 4 weeks treatment up to a maximum of 6 months supply for doses between 30 and 180 mg per day according to the patient's response and tolerability. Intact PTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.

"Sustained" means the abnormality was detected on at least 2 blood samples collected over a period of 2 to 4 months.

Note

Special Pricing Arrangements apply.

9625N	cinacalcet 30 mg tablet, 28	2	5	..	*408.12		Sensipar	AN
9626P	cinacalcet 60 mg tablet, 28	2	5	..	*809.48		Sensipar	AN
9627Q	cinacalcet 90 mg tablet, 28	2	5	..	*1204.52		Sensipar	AN

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer	
					Price for Max. Qty \$		

ANTIINFECTIVES FOR SYSTEMIC USE

ANTIBACTERIALS FOR SYSTEMIC USE

MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

Macrolides

AZITHROMYCIN

Authority required

Prophylaxis against Mycobacterium avium complex infections in HIV-positive patients with CD4 cell counts of less than 75 per cubic millimetre

6221K	azithromycin 600 mg tablet, 8	2	5	..	*139.94	Zithromax	PF

CLARITHROMYCIN

Authority required

Treatment of Mycobacterium avium complex infections

6151R	clarithromycin 250 mg tablet, 100	1	2	..	28.76	Klacid	GO

6152T	clarithromycin 500 mg tablet, 100	1	2	..	50.68	Klacid	GO

ANTIMYCOBACTERIALS

DRUGS FOR TREATMENT OF TUBERCULOSIS

Antibiotics

RIFABUTIN

Authority required

Treatment of Mycobacterium avium complex infections in HIV-positive patients

Authority required

Prophylaxis against Mycobacterium avium complex infections in HIV-positive patients with CD4 cell counts of less than 75 per cubic millimetre

6195C	rifabutin 150 mg capsule, 30	4	5	..	*680.00	Mycobutin	PF

ANTIVIRALS FOR SYSTEMIC USE

DIRECT ACTING ANTIVIRALS

Nucleosides and nucleotides excl. reverse transcriptase inhibitors

GANCICLOVIR

Authority required

Cytomegalovirus retinitis in severely immunocompromised patients

Authority required

Prophylaxis of cytomegalovirus disease in bone marrow transplant patients at risk of cytomegalovirus disease

Authority required

Prophylaxis of cytomegalovirus disease in solid organ transplant patients at risk of cytomegalovirus disease

6136Y	ganciclovir 500 mg injection, 5 x 500 mg vials	2	1	..	*589.16	Cymevene	RO

VALACICLOVIR

Authority required

Prophylaxis of cytomegalovirus (CMV) infection and disease following renal transplantation in patients at risk of CMV disease

6280M	valaciclovir 500 mg tablet, 100	5	2	..	*637.01	^a APO-Valaciclovir	TX

	^a Valaciclovir RBX	RA

	^a Valtrex	AS

	^a Zelitrex	UA

VALGANCICLOVIR

Authority required

Cytomegalovirus retinitis in patients with acquired immunodeficiency syndrome

Authority required

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty	Brand Name and Manufacturer	
					\$		
Prophylaxis of cytomegalovirus infection and disease in solid organ transplant patients at risk of cytomegalovirus disease							
6357N	valganciclovir 450 mg tablet, 60	2	5	..	*4538.36	Valcyte	RO
9675F	valganciclovir 50 mg/mL oral liquid: powder for, 100 ml	11	5	..	*#4624.22	Valcyte	RO

Phosphonic acid derivatives

FOSCARNET

Authority required

Treatment of cytomegalovirus retinitis in patients with AIDS

Authority required

Treatment of aciclovir-resistant herpes simplex virus infection in immunocompromised patients with HIV infection

6134W	FOSCARNET SODIUM I.V. infusion 24 mg per mL, 250 mL bottle, 6	1	1	..	1224.26	Foscavir	IX

Protease inhibitors

ATAZANAVIR

Authority required

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naive,

AND

The treatment must be in combination with other antiretroviral agents.

Authority required

HIV infection

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received PBS-subsidised therapy for HIV infection,

AND

The treatment must be in combination with other antiretroviral agents.

6451M	atazanavir 150 mg capsule, 60	2	5	..	*1090.58	Reyataz	BQ
6452N	atazanavir 200 mg capsule, 60	2	5	..	*1438.52	Reyataz	BQ
9614B	atazanavir 300 mg capsule, 30	2	5	..	*1090.58	Reyataz	BQ

BOCEPREVIR

Authority required

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease,

AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

AND

The treatment must be in combination with peginterferon alfa and ribavirin,

AND

The treatment must be limited to a maximum duration of 32 weeks in patients without hepatic cirrhosis who were partial responders or relapsers to the prior course of interferon based therapy for hepatitis C; OR

The treatment must be limited to a maximum duration of 44 weeks in patients without hepatic cirrhosis who were null responders to the prior course of interferon based therapy for hepatitis C; OR

The treatment must be limited to a maximum duration of 44 weeks for all patients with hepatic cirrhosis,

AND

The treatment must cease after the first 8 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 12,

AND

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	
	The treatment must cease after the first 20 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 24.					
	Population criteria:					
	Patient must be 18 years or older,					
	AND					
	Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.					
	Treatment criteria:					
	Must be treated in an accredited treatment centre.					
	Chronic genotype 1 hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.					
	Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised boceprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records.					
	For patients without hepatic cirrhosis who were partial responders or relapsers to the prior course of interferon based therapy, a maximum of 7 repeats may be prescribed.					
	For patients without hepatic cirrhosis who were null responders to the prior course of interferon based therapy, a maximum of 10 repeats may be prescribed.					
	For patients with hepatic cirrhosis, a maximum of 10 repeats may be prescribed.					
	<u>Authority required</u>					
	Chronic genotype 1 hepatitis C infection					
	Clinical criteria:					
	Patient must have compensated liver disease,					
	AND					
	Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,					
	AND					
	The treatment must be in combination with peginterferon alfa and ribavirin,					
	AND					
	The treatment must be limited to a maximum duration of 24 weeks in patients without hepatic cirrhosis; OR					
	The treatment must be limited to a maximum duration of 44 weeks in patients with hepatic cirrhosis,					
	AND					
	The treatment must cease after the first 20 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 24.					
	Population criteria:					
	Patient must be 18 years or older,					
	AND					
	Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.					
	Treatment criteria:					
	Must be treated in an accredited treatment centre.					
	Evidence of chronic genotype 1 hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.					
	Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised boceprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records.					
	For patients without hepatic cirrhosis, a maximum of 5 repeats may be prescribed.					
	For patients with hepatic cirrhosis, a maximum of 10 repeats may be prescribed.					
	<u>Note</u>					
	No increase in the maximum quantity or number of units may be authorised.					
	<u>Note</u>					
	Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:					
	(a) a nurse educator/counsellor for patients; and					
	(b) 24-hour access by patients to medical advice; and					
	(c) an established liver clinic.					
2435F	Boceprevir 200 mg capsule, 336 capsules	1	10	..	3966.76	Victrelis MK

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer	
					Price for Max. Qty \$		
DARUNAVIR							
<u>Authority required</u>							
Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents, and co-administered with 100 mg ritonavir twice daily in an antiretroviral experienced patient who, after at least one antiretroviral regimen, has experienced virological failure or clinical failure or genotypic resistance.							
Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity							
9581G	darunavir 150 mg tablet, 240	1	5	..	1095.47	Prezista	JC
5000E	darunavir 600 mg tablet, 60	2	5	..	*2144.18	Prezista	JC
DARUNAVIR							
<u>Authority required</u>							
Human immunodeficiency virus (HIV) infection							
Clinical criteria:							
The treatment must be in addition to optimised background therapy,							
AND							
The treatment must be in combination with other antiretroviral agents,							
AND							
The treatment must be co-administered with 100 mg ritonavir,							
AND							
Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen,							
AND							
Patient must not have demonstrated darunavir resistance associated mutations detected on resistance testing.							
Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.							
10000H	darunavir 800 mg tablet, 30	2	5	..	*1445.04	Prezista	JC
FOSAMPRENAVIR							
<u>Authority required</u>							
HIV infection							
Treatment Phase: Initial							
Clinical criteria:							
Patient must be antiretroviral treatment naive,							
AND							
The treatment must be in combination with other antiretroviral agents.							
<u>Authority required</u>							
HIV infection							
Treatment Phase: Continuing							
Clinical criteria:							
Patient must have previously received PBS-subsidised therapy for HIV infection,							
AND							
The treatment must be in combination with other antiretroviral agents.							
6454Q	fosamprenavir 50 mg/mL oral liquid, 225 mL	8	5	..	*851.72	Telzir	VI
6453P	fosamprenavir 700 mg tablet, 60	2	5	..	*795.42	Telzir	VI

INDINAVIR

Authority required

HIV infection

Treatment Phase: Initial

Clinical criteria:

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer	
					Price for Max. Qty \$		
	Patient must be antiretroviral treatment naive, AND The treatment must be in combination with other antiretroviral agents. <u>Authority required</u> HIV infection Treatment Phase: Continuing Clinical criteria: Patient must have previously received PBS-subsidised therapy for HIV infection, AND The treatment must be in combination with other antiretroviral agents.						
6202K	indinavir 400 mg capsule, 180	2	5	..	*953.16	Crixivan 400 mg	MK
	RITONAVIR <u>Authority required</u> HIV infection Treatment Phase: Initial Clinical criteria: Patient must be antiretroviral treatment naive, AND The treatment must be in combination with other antiretroviral agents. <u>Authority required</u> HIV infection Treatment Phase: Continuing Clinical criteria: Patient must have previously received PBS-subsidised therapy for HIV infection, AND The treatment must be in combination with other antiretroviral agents.						
9677H	ritonavir 100 mg tablet, 30	24	5	..	*1028.92	Norvir	VE
6494T	ritonavir 600 mg/7.5 mL oral liquid, 90 mL	10	5	..	*953.16	Norvir	VE
	SAQUINAVIR <u>Authority required</u> HIV infection Treatment Phase: Initial Clinical criteria: Patient must be antiretroviral treatment naive, AND The treatment must be in combination with other antiretroviral agents. <u>Authority required</u> HIV infection Treatment Phase: Continuing Clinical criteria: Patient must have previously received PBS-subsidised therapy for HIV infection, AND The treatment must be in combination with other antiretroviral agents.						
6498B	saquinavir 500 mg tablet, 120	2	5	..	*1057.88	Invirase	RO
	SIMEPREVIR <u>Authority required</u> Chronic genotype 1 hepatitis C infection Clinical criteria:						

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	Patient must have compensated liver disease, AND Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, AND The treatment must be in combination with peginterferon alfa and ribavirin, AND The treatment must be limited to a maximum duration of 12 weeks, AND The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is 25 IU/mL or greater. Population criteria: Patient must be aged 18 years or older, AND Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age. Treatment criteria: Must be treated in an accredited treatment centre. Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records. Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised simeprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records.					
	<u>Authority required</u> Chronic genotype 1 hepatitis C infection Clinical criteria: Patient must have compensated liver disease, AND Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C, AND The treatment must be in combination with peginterferon alfa and ribavirin, AND The treatment must be limited to a maximum duration of 12 weeks, AND The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is 25 IU/mL or greater. Population criteria: Patient must be 18 years or older, AND Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age. Treatment criteria: Must be treated in an accredited treatment centre. Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records. Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised simeprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records.					
	<u>Note</u> No increase in the maximum quantity or number of units may be authorised. <u>Note</u> No increase in the maximum number of repeats may be authorised. <u>Note</u> Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer	
					Price for Max. Qty \$		
	hepatitis C: (a) a nurse educator/counsellor for patients; and (b) 24-hour access by patients to medical advice; and (c) an established liver clinic.						
10197Q	simeprevir sodium 150 mg capsule, 7	6	..	..	*14912.50	Olysio	JC

TELAPREVIR

Authority required

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease,

AND

Patient must not have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

AND

The treatment must be in combination with peginterferon alfa and ribavirin,

AND

The treatment must be limited to a maximum duration of 12 weeks,

AND

The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL.

Population criteria:

Patient must be 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised telaprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records.

Authority required

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease,

AND

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

AND

The treatment must be in combination with peginterferon alfa and ribavirin,

AND

The treatment must be limited to a maximum duration of 12 weeks,

AND

The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL.

Population criteria:

Patient must be 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised telaprevir, except where

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.	Brand Name and Manufacturer
					Qty \$	
	the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records.					
	<u>Note</u>					
	No increase in the maximum quantity or number of units may be authorised.					
	<u>Note</u>					
	No increase in the maximum number of repeats may be authorised.					
	<u>Note</u>					
	Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:					
	(a) a nurse educator/counsellor for patients; and					
	(b) 24-hour access by patients to medical advice; and					
	(c) an established liver clinic.					
2378E	telaprevir 375 mg tablet, 42	6	..	..	*14912.50	Incivo

TIPRANAVIR

Authority required

Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents, and co-administered with 200 mg ritonavir twice daily in an antiretroviral experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity

Note

Special Pricing Arrangements apply.

9610T	tipranavir 250 mg capsule, 120	2	5	..	*2188.76	Aptivus	BY

Nucleoside and nucleotide reverse transcriptase inhibitors

ABACAVIR

Authority required

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naive,

AND

The treatment must be in combination with other antiretroviral agents.

Authority required

HIV infection

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received PBS-subsidised therapy for HIV infection,

AND

The treatment must be in combination with other antiretroviral agents.

6265R	abacavir 20 mg/mL oral liquid, 240 mL	8	5	..	*690.20	Ziagen	VI
6264Q	abacavir 300 mg tablet, 60	2	5	..	*593.32	Ziagen	VI

ADEFOVIR DIPIVOXIL

Authority required

Chronic hepatitis B in a patient without cirrhosis who has failed antihepadnaviral therapy and who satisfies all of the following criteria:

(a) Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or

(b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance

Authority required

Chronic hepatitis B in a patient with cirrhosis who has failed antihepadnaviral therapy and who has detectable HBV DNA.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer	
					Qty	\$		

micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy

Note

Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

6450L	adefovir dipivoxil 10 mg tablet, 30	2	5	..	*1096.76	^a	APO-Adefovir	TX
						^a	Hepsera	GI

DIDANOSINE

Authority required

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naive,

AND

The treatment must be in combination with other antiretroviral agents.

Authority required

HIV infection

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received PBS-subsidised therapy for HIV infection,

AND

The treatment must be in combination with other antiretroviral agents.

6298L	didanosine 125 mg capsule: enteric, 30	2	5	..	*298.86		Videx EC	BQ
6299M	didanosine 200 mg capsule: enteric, 30	2	5	..	*346.64		Videx EC	BQ
6300N	didanosine 250 mg capsule: enteric, 30	2	5	..	*431.58		Videx EC	BQ
6301P	didanosine 400 mg capsule: enteric, 30	2	5	..	*686.48		Videx EC	BQ

EMTRICITABINE

Authority required

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naive,

AND

The treatment must be in combination with other antiretroviral agents.

Authority required

HIV infection

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received PBS-subsidised therapy for HIV infection,

AND

The treatment must be in combination with other antiretroviral agents.

6137B	emtricitabine 200 mg capsule, 30	2	5	..	*593.32		Emtriva	GI

ENTECAVIR

Authority required

Chronic hepatitis B in a patient without cirrhosis who has failed lamivudine and who satisfies all of the following criteria:

(a) Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or

(b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance

Authority required

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					Price for Max. Qty \$		

Chronic hepatitis B in a patient with cirrhosis who has failed lamivudine and who has detectable HBV DNA.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy

Note

PBS-subsidised entecavir monohydrate must be used as monotherapy.

9603K	entecavir monohydrate 1 mg tablet, 30	2	5	..	*1296.76	Baraclude	BQ

ENTECAVIR

Authority required

Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria:

(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;

(2) Evidence of chronic liver injury as determined by:

(a) Confirmed elevated serum ALT; or

(b) Liver biopsy

Authority required

Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy

Note

PBS-subsidised entecavir monohydrate must be used as monotherapy.

9602J	entecavir monohydrate 500 microgram tablet, 30	2	5	..	*806.10	Baraclude	BQ

LAMIVUDINE

Authority required

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naive,

AND

The treatment must be in combination with other antiretroviral agents.

Authority required

HIV infection

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received PBS-subsidised therapy for HIV infection,

AND

The treatment must be in combination with other antiretroviral agents.

6194B	lamivudine 10 mg/mL oral liquid, 240 mL	8	5	..	*472.52	3TC	VI
6193Y	lamivudine 150 mg tablet, 60	2	5	..	*325.70	^a 3TC	VI
						^a Lamivudine	AF
						^a Alphapharm	
						^a Lamivudine RBX	RA
6435Q	lamivudine 300 mg tablet, 30	2	5	..	*325.70	^a 3TC	VI
						^a Lamivudine	AF
						^a Alphapharm	
						^a Lamivudine RBX	RA

LAMIVUDINE

Authority required

Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria:

(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					Price for Max. Qty \$		
	(2) Evidence of chronic liver injury as determined by:						
	(a) Confirmed elevated serum ALT; or						
	(b) Liver biopsy						
	<u>Authority required</u>						
	Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA.						
	Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy						
6257H	lamivudine 100 mg tablet, 28	2	5	..	*175.70	^a Zeffix	AS
						^a Zetlam	AF
6271C	lamivudine 5 mg/mL oral liquid, 240 mL	5	5	..	*242.06	Zeffix	AS

STAVUDINE

Authority required

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naive,

AND

The treatment must be in combination with other antiretroviral agents.

Authority required

HIV infection

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received PBS-subsidised therapy for HIV infection,

AND

The treatment must be in combination with other antiretroviral agents.

6186N	stavudine 20 mg capsule, 60	2	5	..	*589.16		Zerit	BQ
6189R	stavudine 30 mg capsule, 60	2	5	..	*700.82		Zerit	BQ
6190T	stavudine 40 mg capsule, 60	2	5	..	*932.16		Zerit	BQ

TELBIVUDINE

Authority required

Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B without cirrhosis who is nucleoside analogue naive and satisfies all of the following criteria:

(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented hepatitis B infection;

(2) Evidence of chronic liver injury as determined by:

(a) Confirmed elevated serum ALT; or

(b) Liver biopsy

Authority required

Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B with cirrhosis who is nucleoside analogue naive and who has detectable HBV DNA.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy

9630W	telbivudine 600 mg tablet, 28	2	5	..	*528.60		Sebivo	NV

TENOFOVIR

Authority required

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naive,

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	AND The treatment must be in combination with other antiretroviral agents. <u>Authority required</u> HIV infection Treatment Phase: Continuing Clinical criteria: Patient must have previously received PBS-subsidised therapy for HIV infection, AND The treatment must be in combination with other antiretroviral agents. <u>Authority required</u> Chronic hepatitis B Clinical criteria: Patient must not have cirrhosis, AND Patient must be nucleoside analogue naive, AND Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, AND Patient must have evidence of chronic liver injury determined by: (i) confirmed elevated serum ALT; or (ii) liver biopsy, AND The treatment must be the sole PBS-subsidised therapy for this condition. <u>Note</u> Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy. <u>Authority required</u> Chronic hepatitis B Clinical criteria: Patient must have cirrhosis, AND Patient must be nucleoside analogue naive, AND Patient must have detectable HBV DNA, AND The treatment must be the sole PBS-subsidised therapy for this condition. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy. <u>Note</u> Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy. <u>Authority required</u> Chronic hepatitis B Clinical criteria: Patient must not have cirrhosis, AND Patient must have failed antihepadnaviral therapy, AND Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; OR Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance. <u>Note</u> Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	
<u>Authority required</u>						
Chronic hepatitis B						
Clinical criteria:						
Patient must have cirrhosis,						
AND						
Patient must have failed antihepadnaviral therapy,						
AND						
Patient must have detectable HBV DNA.						
Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.						
<u>Note</u>						
Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.						
6358P	tenofovir disoproxil fumarate 300 mg tablet, 30	2	5	..	*1011.60	Viread

ZIDOVUDINE

Authority required

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naive,

AND

The treatment must be in combination with other antiretroviral agents.

Authority required

HIV infection

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received PBS-subsidised therapy for HIV infection,

AND

The treatment must be in combination with other antiretroviral agents.

6153W	zidovudine 100 mg capsule, 100	4	5	..	*861.48		Retrovir	VI
6154X	zidovudine 250 mg capsule, 40	6	5	..	*1279.54		Retrovir	VI
6155Y	zidovudine 50 mg/5 mL oral liquid, 200 mL	15	5	..	*706.96		Retrovir	VI

Non-nucleoside reverse transcriptase inhibitors

EFAVIRENZ

Authority required

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naive,

AND

The treatment must be in combination with other antiretroviral agents.

Authority required

HIV infection

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received PBS-subsidised therapy for HIV infection,

AND

The treatment must be in combination with other antiretroviral agents.

9618F	efavirenz 200 mg tablet, 90	2	5	..	*571.64		Stocrin	MK
6372J	efavirenz 30 mg/mL oral liquid, 180 mL	7	5	..	*599.87		Stocrin	MK

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer	
					Price for Max. Qty \$		
6356M	efavirenz 600 mg tablet, 30	2	5	..	*571.64	Stocrin	MK

ETRAVIRINE

Authority required

Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents in an antiretroviral experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity

5062K	etravirine 200 mg tablet, 60	2	5	..	*1279.76	Intelence	JC

NEVIRAPINE

Authority required

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naive,

AND

The treatment must be in combination with other antiretroviral agents.

Authority required

HIV infection

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received PBS-subsidised therapy for HIV infection,

AND

The treatment must be in combination with other antiretroviral agents.

9571R	nevirapine 10 mg/mL oral liquid, 240 mL	10	5	..	*1396.76	Viramune	BY
6215D	nevirapine 200 mg tablet, 60	2	5	..	*418.78	^a Nevipin	GN
						^a Nevirapine Alphapharm	AF
						^a Nevirapine RBX	RA
						^a Viramune	BY

NEVIRAPINE

Authority required

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must have been stabilised on nevirapine immediate release,

AND

The treatment must be in combination with other antiretroviral agents.

Authority required

HIV infection

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received PBS-subsidised therapy for HIV infection,

AND

The treatment must be in combination with other antiretroviral agents.

1129K	nevirapine 400 mg tablet: modified release, 30 tablets	2	5	..	*418.78	Viramune XR	BY

RILPIVIRINE

Authority required

HIV infection

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.	Brand Name and Manufacturer	
					Qty \$		
	Treatment Phase: Initial						
	Clinical criteria:						
	Patient must be antiretroviral treatment naive,						
	AND						
	The treatment must be in combination with other antiretroviral agents.						
	<u>Authority required</u>						
	HIV infection						
	Treatment Phase: Continuing						
	Clinical criteria:						
	Patient must have previously received PBS-subsidised therapy for HIV infection,						
	AND						
	The treatment must be in combination with other antiretroviral agents.						
1170N	rilpivirine 25 mg tablet, 30	2	5	..	*571.64	Edurant	JC

Antivirals for treatment of HIV infections, combinations

ABACAVIR + LAMIVUDINE

Authority required

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naive,

AND

The treatment must be in combination with other antiretroviral agents.

Population criteria:

Patient must be aged 12 years or older,

AND

Patient must weigh 40 kg or more.

Authority required

HIV infection

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received PBS-subsidised therapy for HIV infection,

AND

The treatment must be in combination with other antiretroviral agents.

Population criteria:

Patient must be aged 12 years or older,

AND

Patient must weigh 40 kg or more.

6458X	abacavir 600 mg + lamivudine 300 mg tablet, 30	2	5	..	*912.26	Kivexa	VI

ABACAVIR + LAMIVUDINE + ZIDOVUDINE

Authority required

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naive.

Population criteria:

Patient must be aged 12 years or older,

AND

Patient must weigh 40 kg or more.

Authority required

HIV infection

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.	Brand Name and Manufacturer	
					Qty \$		
	Treatment Phase: Continuing						
	Clinical criteria:						
	Patient must have previously received PBS-subsidised therapy for HIV infection.						
	Population criteria:						
	Patient must be aged 12 years or older,						
	AND						
	Patient must weigh 40 kg or more.						
6327B	abacavir 300 mg + lamivudine 150 mg + zidovudine 300 mg tablet, 60	2	5	..	*1404.04	Trizivir	VI
	DOLUTEGRAVIR + ABACAVIR + LAMIVUDINE						
	<u>Authority required</u>						
	HIV infection						
	Treatment Phase: Initial						
	Clinical criteria:						
	Patient must be antiretroviral treatment naive.						
	Population criteria:						
	Patient must be aged 12 years or older,						
	AND						
	Patient must weigh 40 kg or more.						
	<u>Authority required</u>						
	HIV infection						
	Treatment Phase: Continuing						
	Clinical criteria:						
	Patient must have previously received PBS-subsidised therapy for HIV infection.						
	Population criteria:						
	Patient must be aged 12 years or older,						
	AND						
	Patient must weigh 40 kg or more.						
10248J	dolutegravir 50 mg + abacavir 600 mg + lamivudine 300 mg tablet, 30	2	5	..	*2120.12	Triumeq	VI
	EMTRICITABINE + RILPIVIRINE + TENOFOVIR						
	<u>Authority required</u>						
	HIV infection						
	Treatment Phase: Initial						
	Clinical criteria:						
	Patient must be antiretroviral treatment naive.						
	<u>Authority required</u>						
	HIV infection						
	Treatment Phase: Continuing						
	Clinical criteria:						
	Patient must have previously received PBS-subsidised therapy for HIV infection.						
1490K	emtricitabine 200 mg + rilpivirine 25 mg + tenofovir disoproxil fumarate 300 mg tablet, 30	2	5	..	*2120.12	Eviplera	GI
	LAMIVUDINE + ZIDOVUDINE						
	<u>Authority required</u>						
	HIV infection						
	Treatment Phase: Initial						
	Clinical criteria:						
	Patient must be antiretroviral treatment naive,						
	AND						
	The treatment must be in combination with other antiretroviral agents.						
	<u>Authority required</u>						

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer	
					Qty	\$		
	HIV infection Treatment Phase: Continuing Clinical criteria: Patient must have previously received PBS-subsidised therapy for HIV infection, AND The treatment must be in combination with other antiretroviral agents.							
6234D	lamivudine 150 mg + zidovudine 300 mg tablet, 60	2	5	..	*825.72	^a	Combivir	VI
						^a	Lamivudine 150 mg + Zidovudine 300 mg Alphapharm	AF
	LOPINAVIR + RITONAVIR <u>Authority required</u> HIV infection Treatment Phase: Initial Clinical criteria: Patient must be antiretroviral treatment naive, AND The treatment must be in combination with other antiretroviral agents. <u>Authority required</u> HIV infection Treatment Phase: Continuing Clinical criteria: Patient must have previously received PBS-subsidised therapy for HIV infection, AND The treatment must be in combination with other antiretroviral agents.							
9633B	lopinavir 100 mg + ritonavir 25 mg tablet, 60	2	5	..	*362.96		Kaletra	VE
6495W	lopinavir 200 mg + ritonavir 50 mg tablet, 120	2	5	..	*1416.76		Kaletra	VE
6341R	lopinavir 400 mg/5 mL + ritonavir 100 mg/5 mL oral liquid, 60 mL	10	5	..	*1336.76		Kaletra	VE
	TENOFOVIR + EMTRICITABINE <u>Authority required</u> HIV infection Treatment Phase: Initial Clinical criteria: Patient must be antiretroviral treatment naive, AND The treatment must be in combination with other antiretroviral agents. <u>Authority required</u> HIV infection Treatment Phase: Continuing Clinical criteria: Patient must have previously received PBS-subsidised therapy for HIV infection, AND The treatment must be in combination with other antiretroviral agents.							
6468K	tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg tablet, 30	2	5	..	*1576.96		Truvada	GI

TENOFOVIR + EMTRICITABINE + EFAVIRENZ

Authority required

HIV infection

Treatment Phase: Initial

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer	
	Clinical criteria:						
	Patient must be antiretroviral treatment naive.						
	<u>Authority required</u>						
	HIV infection						
	Treatment Phase: Continuing						
	Clinical criteria:						
	Patient must have previously received PBS-subsidised therapy for HIV infection.						
9650X	tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg + efavirenz 600 mg tablet, 30	2	5	..	*2120.12	Atripla	GI
	TENOFOVIR + EMTRICITABINE + ELVITEGRAVIR + COBICISTAT						
	<u>Authority required</u>						
	HIV infection						
	Treatment Phase: Initial						
	Clinical criteria:						
	Patient must be antiretroviral treatment naive.						
	<u>Authority required</u>						
	HIV infection						
	Treatment Phase: Continuing						
	Clinical criteria:						
	Patient must have previously received PBS-subsidised therapy for HIV infection.						
10085T	tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg + elvitegravir 150 mg + cobicistat 150 mg tablet, 30	2	5	..	*2120.12	Stribild	GI
	Other antirvirals						
	DOLUTEGRAVIR						
	<u>Authority required</u>						
	HIV infection						
	Treatment Phase: Initial						
	Clinical criteria:						
	Patient must be antiretroviral treatment naive,						
	AND						
	The treatment must be in combination with other antiretroviral agents.						
	<u>Authority required</u>						
	HIV infection						
	Treatment Phase: Continuing						
	Clinical criteria:						
	Patient must have previously received PBS-subsidised therapy for HIV infection,						
	AND						
	The treatment must be in combination with other antiretroviral agents.						
10070B	dolutegravir 50 mg tablet, 30	2	5	..	*1377.86	Tivicay	VI
	ENFUVIRTIDE						
	<u>Authority required</u>						
	Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents in an antiretroviral experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance.						
	Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity						
6455R	enfuvirtide 90 mg injection [60 x 90 mg vials] (&) inert substance diluent [60 x 1.1 mL vials], 1 pack	2	5	..	*4472.76	Fuzeon	RO
	MARAVIROC						
	<u>Authority required</u>						
	Treatment, in addition to optimised background therapy in combination with other antiretroviral agents, of an antiretroviral experienced patient infected with only CCR5-tropic HIV-1, who, after each of at least three different antiretroviral regimens that have included one drug from at least 3						

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					Qty \$		
	different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance. A tropism assay to determine CCR5 only strain status is required prior to initiation. Individuals with CXCR4 tropism demonstrated at any time point are not eligible.						
	Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity						
9572T	maraviroc 150 mg tablet, 60	2	5	..	*1882.16	Celsentri	VI
9573W	maraviroc 300 mg tablet, 60	2	5	..	*1882.16	Celsentri	VI

RALTEGRAVIR

Authority required

HIV infection

Treatment Phase: Initial

Clinical criteria:

The treatment must be in combination with other antiretroviral agents,

AND

Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy,

AND

Patient must have a CD4 count of less than 500 per cubic millimetre; OR

Patient must have symptomatic HIV disease.

Population criteria:

Patient must be aged 2 years or older.

Authority required

HIV infection

Treatment Phase: Continuing

Clinical criteria:

The treatment must be in combination with other antiretroviral agents,

AND

Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy,

AND

Patient must have previously received PBS-subsidised therapy for HIV infection.

Population criteria:

Patient must be aged 2 years or older.

2754Y	raltegravir 100 mg tablet: chewable, 60	6	5	..	*2071.78	Isentress	MK
2743J	raltegravir 25 mg tablet: chewable, 60	6	5	..	*533.32	Isentress	MK

RALTEGRAVIR

Authority required

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naive,

AND

The treatment must be in combination with other antiretroviral agents.

Authority required

HIV infection

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received PBS-subsidised therapy for HIV infection,

AND

The treatment must be in combination with other antiretroviral agents.

9629T	raltegravir 400 mg tablet, 60	2	5	..	*1377.86	Isentress	MK

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					Price for Max.	Qty	
					\$	\$	

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

ANTINEOPLASTIC AGENTS

ANTIMETABOLITES

Pyrimidine analogues

AZACITIDINE

Authority required

Initial PBS-subsidised treatment of a patient with:

- (1) Myelodysplastic syndrome classified as Intermediate-2 or high risk according to the International Prognostic Scoring System (IPSS); OR
- (2) Chronic Myelomonocytic Leukaemia (10% to 29% marrow blasts without Myeloproliferative Disorder); OR
- (3) Acute Myeloid Leukaemia with 20 to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification.

Classification of a patient as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations:

1. 11% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 0 to 1 cytopenias; OR
2. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR
3. 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
4. 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
5. 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; OR
6. less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias.

Classification of a patient as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations:

1. 21% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
2. 21% to 30% marrow blasts with intermediate (other abnormalities) or poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
3. 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
4. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias.

The first authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and
- (c) a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome, chronic myelomonocytic leukaemia or acute myeloid leukaemia; and
- (d) a copy of the full blood examination report; and
- (e) for myelodysplastic syndrome, a copy of the pathology report detailing the cytogenetics demonstrating intermediate-2 or high risk disease according to the International Prognostic Scoring System (IPSS); and
- (f) a signed patient acknowledgment form.

No more than three cycles will be authorised

Note

Any queries concerning the arrangements to prescribe azacitidine may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe azacitidine should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

Special Pricing Arrangements apply.

6100C	azacitidine 100 mg injection, 1 x 100 mg vial	14	2	..	*7746.80	Vidaza	CJ

AZACITIDINE

Authority required

Continuing treatment of a patient with:

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.	Brand Name and Manufacturer
					Qty \$	
	(1) Myelodysplastic syndrome classified as Intermediate-2 or high risk according to the International Prognostic Scoring System (IPSS); OR (2) Chronic Myelomonocytic Leukaemia (10% to 29% marrow blasts without Myeloproliferative Disorder); OR (3) Acute Myeloid Leukaemia with 20 to 30% blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification; who has previously been issued with an authority prescription for azacitidine and does not have progressive disease. Authority applications for continuing treatment may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Up to six cycles will be authorised					
	<u>Note</u> Any queries concerning the arrangements to prescribe azacitidine may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au . Written applications for authority to prescribe azacitidine should be forwarded to: Medicare Australia Prior Written Approval of Specialised Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001					
	<u>Note</u> Special Pricing Arrangements apply.					
6138C	azacitidine 100 mg injection, 1 x 100 mg vial	14	5	..	*7746.80	Vidaza

CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

Anthracyclines and related substances

DOXORUBICIN HYDROCHLORIDE-PEGYLATED LIPOSOMAL

Authority required

Treatment of AIDS-related Kaposi's sarcoma in patients with CD4 cell counts of less than 200 per cubic millimetre and extensive mucocutaneous involvement

Authority required

Treatment of AIDS-related Kaposi's sarcoma in patients with CD4 cell counts of less than 200 per cubic millimetre and extensive visceral involvement

6249X	doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial	4	5	..	*2140.00	^a Caelyx	JC
						^a Liposomal Doxorubicin SUN	ZF

OTHER ANTINEOPLASTIC AGENTS

Monoclonal antibodies

ALEMTUZUMAB

Authority required

Multiple sclerosis

Treatment Phase: Initial

Clinical criteria:

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient,

AND

The treatment must be as monotherapy,

AND

Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years,

AND

Patient must be ambulatory (without assistance or support).

Treatment criteria:

Must be treated by a neurologist.

Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer	
					Price for Max. Qty \$		
	<u>Note</u> Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.						
	<u>Note</u> Special Pricing Arrangements apply.						
	<u>Note</u> No increase in the maximum quantity or number of units may be authorised.						
	<u>Note</u> No increase in the maximum number of repeats may be authorised.						
10243D	alemtuzumab 12 mg/1.2 mL injection, 1 x 1.2 mL vial	5	..	..	*57016.76	Lemtrada	GZ
	ALEMTUZUMAB <u>Authority required</u> Multiple sclerosis Treatment Phase: Continuing Clinical criteria: Patient must have previously been issued with an authority prescription for this drug, AND Patient must not show continuing progression of disability while on treatment with this drug, AND Patient must not receive more than one PBS-subsidised treatment per year, AND The treatment must be as monotherapy, AND Patient must have demonstrated compliance with, and an ability to tolerate this therapy. Treatment criteria: Must be treated by a neurologist.						
	<u>Note</u> Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.						
	<u>Note</u> Special Pricing Arrangements apply.						
	<u>Note</u> No increase in the maximum quantity or number of units may be authorised.						
	<u>Note</u> No increase in the maximum number of repeats may be authorised.						
10246G	alemtuzumab 12 mg/1.2 mL injection, 1 x 1.2 mL vial	3	..	..	*34228.75	Lemtrada	GZ

IMMUNOSTIMULANTS

IMMUNOSTIMULANTS

Colony stimulating factors

FILGRASTIM

Authority required

For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia

Authority required

Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy

Authority required

A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required

A patient with severe congenital neutropenia (absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, and in whom a bone marrow examination has shown evidence of maturational arrest of the neutrophil lineage)

Authority required

A patient with severe chronic neutropenia (absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty	\$	
	readings at least 2 weeks apart, or evidence of neutrophil dysfunction, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months))						
	Authority required A patient with chronic cyclic neutropenia (absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months))						
	Authority required A patient with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned						
	Authority required Mobilisation of peripheral blood progenitor cells, in a normal volunteer, for use in allogeneic transplantation						
	Authority required A patient receiving marrow-ablative chemotherapy and subsequent bone marrow transplantation						
	Authority required A patient with a non-myeloid malignancy receiving marrow-ablative chemotherapy and subsequent autologous peripheral blood progenitor cell transplantation						
	Authority required A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned						
	Authority required A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned						
	Authority required A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned						
	Authority required A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia						
	Authority required A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide)						
	Authority required A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours						
	Authority required A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours						
	Authority required A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma						
	Authority required A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen)						
	Authority required A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease						
	Authority required A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma						
	Authority required A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Hodgkin disease (first-line chemotherapy with escalated BEACOPP)						
5830W	filgrastim 120 microgram/0.2 mL injection, 10 x 0.2 mL syringes	2	11	..	*894.18		Nivestim HH
1082Y	filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes	2	11	..	*2179.94		TevaGrastim AS

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.	Brand Name and Manufacturer	
					Qty \$		
6291D	filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes	2	11	..	*2179.94	Neupogen	AN
9693E	filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes	2	11	..	*2179.94	Nivestim	HH
2747N	filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes	4	11	..	*2179.92	Zarzio	SZ
6126K	filgrastim 300 microgram/mL injection, 10 x 1 mL vials	2	11	..	*2179.94	Neupogen	AN
6292E	filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes	2	11	..	*3466.38	Neupogen	AN
9695G	filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes	2	11	..	*3466.38	Nivestim	HH
2733W	filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes	4	11	..	*3466.36	Zarzio	SZ
1113N	filgrastim 480 microgram/0.8 mL injection, 10 x 0.8 mL syringes	2	11	..	*3466.38	TevaGrastim	AS
6127L	filgrastim 480 microgram/1.6 mL injection, 10 x 1.6 mL vials	2	11	..	*3466.38	Neupogen	AN

LENOGRASTIM

Authority required

Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for reinfusion into patients with non-myeloid malignancies who have had myeloablative or myelosuppressive therapy

Authority required

Mobilisation of peripheral blood progenitor cells, in normal volunteers, for use in allogeneic transplantation to facilitate harvest of such cells in healthy donors

Authority required

Patients with non-myeloid malignancies receiving marrow-ablative chemotherapy and subsequent peripheral blood progenitor cell or bone marrow transplantation

Authority required

Patients with breast cancer receiving standard dose adjuvant chemotherapy who have had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required

Patients receiving first-line chemotherapy for Hodgkin's disease who have had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin's disease

Authority required

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in rhabdomyosarcoma

Authority required

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Ewing's sarcoma

Authority required

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours

Authority required

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours

Authority required

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma

Authority required

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin's lymphoma (intermediate or high grade)

Authority required

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in osteosarcoma

Authority required

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer	
6337M	LENOGRASTIM Powder for injection 13,400,000 i.u. (105 micrograms) vial, 10	2	11	..	*1071.76	Granocyte 13	HH
6338N	LENOGRASTIM Powder for injection 33,600,000 i.u. (263 micrograms) vial, 10	2	11	..	*2613.96	Granocyte 34	HH

PEGFILGRASTIM

Authority required

For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia

Authority required

A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required

A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required

A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required

A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required

A patient with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia

Authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide)

Authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours

Authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours

Authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma

Authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen)

Authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease

Authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma

Authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Hodgkin disease (first-line chemotherapy with escalated BEACOPP)

6363X	pegfilgrastim 6 mg/0.6 mL injection, 1 x 0.6 mL syringe	1	11	..	1971.76	Neulasta	AN

Interferons

INTERFERON ALFA-2A

Authority required

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer	
Use in the treatment of Philadelphia chromosome positive myelogenous leukaemia in the chronic phase							
<u>Authority required</u>							
Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria:							
(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;							
(2) Evidence of chronic liver injury as determined by:							
(a) Confirmed elevated serum ALT; or							
(b) Liver biopsy							
<u>Authority required</u>							
Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA.							
Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy							
<u>Caution</u>							
Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.							
6210W	interferon alfa-2a 3 million international units/0.5 mL injection, 1 x 0.5 mL syringe	30	5	..	*936.46	Roferon-A	RO
6211X	interferon alfa-2a 4.5 million international units/0.5 mL injection, 1 x 0.5 mL syringe	30	5	..	*1387.66	Roferon-A	RO
6212Y	interferon alfa-2a 6 million international units/0.5 mL injection, 1 x 0.5 mL syringe	30	5	..	*1834.06	Roferon-A	RO
6213B	interferon alfa-2a 9 million international units/0.5 mL injection, 1 x 0.5 mL syringe	30	5	..	*2728.06	Roferon-A	RO

INTERFERON ALFA-2B

Authority required

Adjunctive therapy of malignant melanoma following surgery in patients with nodal involvement

Authority required

Use in the treatment of Philadelphia chromosome positive myelogenous leukaemia in the chronic phase

Authority required

Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria:

(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;

(2) Evidence of chronic liver injury as determined by:

(a) Confirmed elevated serum ALT; or

(b) Liver biopsy

Authority required

Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy

Caution

Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

6246R	interferon alfa-2b 10 million international units/mL injection, 5 x 1 mL vials	3	5	..	*1536.25	Intron A	MK
6253D	interferon alfa-2b 18 million international units/1.2 mL injection, 1 x 1.2 mL cartridge	2	5	..	*378.54	Intron A Redipen	MK
6218G	interferon alfa-2b 18 million international units/3 mL injection, 1 x 3 mL vial	15	5	..	*2727.91	Intron A	MK
6219H	interferon alfa-2b 25 million international units/2.5 mL injection, 1 x 2.5 mL vial	15	5	..	*3770.56	Intron A	MK
6254E	interferon alfa-2b 30 million international units/1.2 mL injection, 1 x 1.2 mL cartridge	2	5	..	*626.40	Intron A Redipen	MK
6255F	interferon alfa-2b 60 million international units/1.2 mL injection, 1 x 1.2 mL cartridge	2	5	..	*1238.36	Intron A Redipen	MK

INTERFERON GAMMA-1B

Authority required

Treatment of chronic granulomatous disease in patients with frequent and severe infections despite adequate prophylaxis with antimicrobial agents

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.	Brand Name and Manufacturer	
					Qty \$		
6148N	interferon gamma-1b 2 million international units (100 microgram/0.5 mL) injection, 6 x 0.5 mL vials	2	11	..	*2768.56	Imukin	BY

PEGINTERFERON ALFA-2A

Authority required

Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B without cirrhosis who satisfies all of the following criteria:

(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;

(2) Evidence of chronic liver injury as determined by:

(a) Confirmed elevated serum ALT; or

(b) Liver biopsy;

(3) Has received no prior peginterferon alfa therapy for the treatment of hepatitis B

Authority required

Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B with cirrhosis who has detectable HBV DNA.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

Treatment is limited to 1 course of treatment for a duration of up to 48 weeks

Authority required

Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no prior interferon alfa or peginterferon alfa treatment for hepatitis C and have a contraindication to ribavirin, who satisfy all of the following criteria:

(1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive);

(2) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.

The treatment course is limited to up to 48 weeks.

Patients may only continue treatment after the first 12 weeks if the result of an HCV RNA quantitative assay (performed at the same laboratory using the same test) shows that the plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop

Caution

Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Note

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24 hour access by patients to medical advice; and

(c) an established liver clinic; and

(d) facilities for safe liver biopsy.

6439X	peginterferon alfa-2a 135 microgram/0.5 mL injection, 4 x 0.5 mL syringes	2	5	..	*2378.56	Pegasys	RO
6449K	peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes	2	5	..	*2747.22	Pegasys	RO

PEGINTERFERON ALFA-2A (&) RIBAVIRIN

Authority required

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease,

AND

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir; OR

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir; OR

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with simeprevir,

AND

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12;

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	
	OR					
	The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR					
	The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at week 4; OR					
	The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR					
	The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapsers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR					
	The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis; OR					
	The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL,					
	AND					
	The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,					
	AND					
	The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,					
	AND					
	The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,					
	AND					
	The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,					
	AND					
	The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,					
	AND					
	The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,					
	AND					
	The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL,					
	AND					
	The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,					
	AND					
	The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.					
	Population criteria:					
	Patient must be aged 18 years or older,					
	AND					
	Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.					
	Treatment criteria:					
	Must be treated in an accredited treatment centre.					
	Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.					
	Note					
	No increase in the maximum quantity or number of units may be authorised.					
	Note					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

No increase in the maximum number of repeats may be authorised.

Note

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

- (a) a nurse educator/counsellor for patients; and
- (b) 24-hour access by patients to medical advice; and
- (c) an established liver clinic.

Authority required

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease,

AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

AND

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and in whom plasma HCV RNA is undetectable by an HCV RNA quantitative assay at week 4; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and for whom the results of an HCV RNA qualitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
	Patient must be aged 18 years or older, AND Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age. Treatment criteria: Must be treated in an accredited treatment centre. Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records. For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary. Note No increase in the maximum quantity or number of units may be authorised. Note No increase in the maximum number of repeats may be authorised. Note Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C: (a) a nurse educator/counsellor for patients; and (b) 24-hour access by patients to medical advice; and (c) an established liver clinic. Authority required Chronic non-genotype 1 hepatitis C infection Clinical criteria: The treatment must be the sole PBS-subsidised treatment for hepatitis C, AND Patient must have compensated liver disease, AND The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C, AND Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated), AND Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C, AND The treatment must be limited to a maximum duration of 48 weeks, AND The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12. Population criteria: Patient must be aged 18 years or older, AND Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age. Treatment criteria: Must be treated in an accredited treatment centre. Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records. Note No increase in the maximum quantity or number of units may be authorised. Note No increase in the maximum number of repeats may be authorised. Note Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C: (a) a nurse educator/counsellor for patients; and (b) 24-hour access by patients to medical advice; and (c) an established liver clinic.						

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer	
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<u>Authority required</u>							
Chronic non-genotype 1 hepatitis C infection							
Clinical criteria:							
The treatment must be the sole PBS-subsidised treatment for hepatitis C,							
AND							
Patient must have compensated liver disease,							
AND							
Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,							
AND							
The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,							
AND							
The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR							
The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR							
The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis,							
AND							
The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,							
AND							
The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.							
Population criteria:							
Patient must be aged 18 years or older,							
AND							
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.							
Treatment criteria:							
Must be treated in an accredited treatment centre.							
Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.							
For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.							
For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.							
For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.							
For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.							
<u>Caution</u>							
Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.							
<u>Caution</u>							
Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.							
<u>Note</u>							
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:							
(a) a nurse educator/counsellor for patients; and							
(b) 24-hour access by patients to medical advice; and							
(c) an established liver clinic.							
6392K	peginterferon alfa-2a 135 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [168 tablets], 1 pack	2	5	..	*3119.60	Pegasys RBV	RO
6394M	peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [112 tablets], 1 pack	2	5	..	*3132.04	Pegasys RBV	RO
6395N	peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [140 tablets], 1 pack	2	5	..	*3292.58	Pegasys RBV	RO
6396P	peginterferon alfa-2a 180 microgram/0.5 mL injection	2	5	..	*3453.12	Pegasys RBV	RO

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	
	[4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [168 tablets], 1 pack					

PEGINTERFERON ALFA-2B (&) RIBAVIRIN

Authority required

Chronic genotype 1 hepatitis C infection

Clinical criteria:

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

AND

Patient must have compensated liver disease,

AND

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

AND

The treatment must be limited to a maximum duration of 48 weeks,

AND

The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

Population criteria:

Patient must weigh at least 27 kg,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

- (a) a nurse educator/counsellor for patients; and
- (b) 24-hour access by patients to medical advice; and
- (c) an established liver clinic.

Authority required

Chronic genotype 1 hepatitis C infection

Clinical criteria:

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

AND

Patient must have compensated liver disease,

AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

AND

The treatment must be limited to a maximum duration of 48 weeks,

AND

The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop.

Population criteria:

Patient must weigh at least 27 kg,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
	using an effective form of contraception if of child-bearing age.						
	Treatment criteria:						
	Must be treated in an accredited treatment centre.						
	Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.						
	For patients who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.						
	Note						
	No increase in the maximum quantity or number of units may be authorised.						
	Note						
	No increase in the maximum number of repeats may be authorised.						
	Note						
	Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:						
	(a) a nurse educator/counsellor for patients; and						
	(b) 24-hour access by patients to medical advice; and						
	(c) an established liver clinic.						
	Authority required						
	Chronic non-genotype 1 hepatitis C infection						
	Clinical criteria:						
	The treatment must be the sole PBS-subsidised treatment for hepatitis C,						
	AND						
	Patient must have compensated liver disease,						
	AND						
	The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,						
	AND						
	Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),						
	AND						
	Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,						
	AND						
	The treatment must be limited to a maximum duration of 48 weeks,						
	AND						
	The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.						
	Population criteria:						
	Patient must weigh at least 27 kg,						
	AND						
	Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.						
	Treatment criteria:						
	Must be treated in an accredited treatment centre.						
	Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.						
	Note						
	No increase in the maximum quantity or number of units may be authorised.						
	Note						
	No increase in the maximum number of repeats may be authorised.						
	Note						
	Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:						
	(a) a nurse educator/counsellor for patients; and						
	(b) 24-hour access by patients to medical advice; and						
	(c) an established liver clinic.						
	Authority required						
	Chronic non-genotype 1 hepatitis C infection						
	Clinical criteria:						
	The treatment must be the sole PBS-subsidised treatment for hepatitis C,						

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	AND Patient must have compensated liver disease, AND Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, AND The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C, AND The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis, AND The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, AND The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24. Population criteria: Patient must weigh at least 27 kg, AND Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age. Treatment criteria: Must be treated in an accredited treatment centre. Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records. For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary. For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12. For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed. For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed. Note Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C: (a) a nurse educator/counsellor for patients; and (b) 24-hour access by patients to medical advice; and (c) an established liver clinic. Authority required Chronic genotype 1 hepatitis C infection Clinical criteria: Patient must have compensated liver disease, AND Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated), AND Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir; OR Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir; OR Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with simeprevir, AND The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
	boceprevir who were prior treatment partial responders or relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR						
	The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at week 4; OR						
	The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR						
	The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapsers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR						
	The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis; OR						
	The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL,						
	AND						
	The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,						
	AND						
	The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,						
	AND						
	The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,						
	AND						
	The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,						
	AND						
	The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,						
	AND						
	The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,						
	AND						
	The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL,						
	AND						
	The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,						
	AND						
	The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.						
	Population criteria:						
	Patient must be aged 18 years or older,						
	AND						
	Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.						
	Treatment criteria:						
	Must be treated in an accredited treatment centre.						
	Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.						
	Note						
	No increase in the maximum quantity or number of units may be authorised.						
	Note						
	No increase in the maximum number of repeats may be authorised.						
	Note						

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:					
	(a) a nurse educator/counsellor for patients; and					
	(b) 24-hour access by patients to medical advice; and					
	(c) an established liver clinic.					
	Authority required					
	Chronic genotype 1 hepatitis C infection					
	Clinical criteria:					
	Patient must have compensated liver disease,					
	AND					
	Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,					
	AND					
	The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR					
	The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR					
	The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and in whom plasma HCV RNA is undetectable by an HCV RNA quantitative assay at week 4; OR					
	The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR					
	The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR					
	The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis; OR					
	The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and for whom the results of an HCV RNA qualitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL,					
	AND					
	The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,					
	AND					
	The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,					
	AND					
	The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,					
	AND					
	The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,					
	AND					
	The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,					
	AND					
	The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL,					
	AND					
	The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,					
	AND					
	The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.					
	Population criteria:					
	Patient must be aged 18 years or older,					
	AND					

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.					
	Treatment criteria:					
	Must be treated in an accredited treatment centre.					
	Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.					
	For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.					
	Note					
	No increase in the maximum quantity or number of units may be authorised.					
	Note					
	No increase in the maximum number of repeats may be authorised.					
	Note					
	Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:					
	(a) a nurse educator/counsellor for patients; and					
	(b) 24-hour access by patients to medical advice; and					
	(c) an established liver clinic.					
	Authority required					
	Chronic non-genotype 1 hepatitis C infection					
	Clinical criteria:					
	The treatment must be the sole PBS-subsidised treatment for hepatitis C,					
	AND					
	Patient must have compensated liver disease,					
	AND					
	The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,					
	AND					
	Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),					
	AND					
	Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,					
	AND					
	The treatment must be limited to a maximum duration of 48 weeks,					
	AND					
	The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.					
	Population criteria:					
	Patient must be aged 18 years or older,					
	AND					
	Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.					
	Treatment criteria:					
	Must be treated in an accredited treatment centre.					
	Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.					
	Note					
	No increase in the maximum quantity or number of units may be authorised.					
	Note					
	No increase in the maximum number of repeats may be authorised.					
	Note					
	Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:					
	(a) a nurse educator/counsellor for patients; and					
	(b) 24-hour access by patients to medical advice; and					
	(c) an established liver clinic.					
	Authority required					
	Chronic non-genotype 1 hepatitis C infection					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer	
					Price for Max. Qty \$		
Clinical criteria:							
The treatment must be the sole PBS-subsidised treatment for hepatitis C,							
AND							
Patient must have compensated liver disease,							
AND							
Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,							
AND							
The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,							
AND							
The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR							
The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR							
The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis,							
AND							
The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,							
AND							
The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.							
Population criteria:							
Patient must be aged 18 years or older,							
AND							
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.							
Treatment criteria:							
Must be treated in an accredited treatment centre.							
Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.							
For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.							
For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.							
For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.							
For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.							
Caution							
Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.							
Caution							
Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.							
Note							
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:							
(a) a nurse educator/counsellor for patients; and							
(b) 24-hour access by patients to medical advice; and							
(c) an established liver clinic.							
6405D	peginterferon alfa-2b 100 microgram injection [4 x 100 microgram cartridges] (&) ribavirin 200 mg capsule [112 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack	2	5	..	*3146.38	Pegatron	MK
6400W	peginterferon alfa-2b 50 microgram injection [4 x 50 microgram cartridges] (&) ribavirin 200 mg capsule [112 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack	2	5	..	*2166.50	Pegatron	MK
6401X	peginterferon alfa-2b 80 microgram injection [4 x 80 microgram cartridges] (&) ribavirin 200 mg capsule [84 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack	2	5	..	*2469.48	Pegatron	MK

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
	PEGINTERFERON ALFA-2B (&) RIBAVIRIN						
	<u>Authority required</u>						
	Chronic genotype 1 hepatitis C infection						
	Clinical criteria:						
	Patient must have compensated liver disease,						
	AND						
	Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),						
	AND						
	Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir; OR						
	Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir; OR						
	Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with simeprevir,						
	AND						
	The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR						
	The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR						
	The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at week 4; OR						
	The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR						
	The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapsers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR						
	The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis; OR						
	The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL,						
	AND						
	The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,						
	AND						
	The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,						
	AND						
	The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,						
	AND						
	The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,						
	AND						
	The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,						
	AND						
	The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,						
	AND						
	The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL,						
	AND						

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,					
	AND					
	The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.					
	Population criteria:					
	Patient must be aged 18 years or older,					
	AND					
	Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.					
	Treatment criteria:					
	Must be treated in an accredited treatment centre.					
	Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.					
	Note					
	No increase in the maximum quantity or number of units may be authorised.					
	Note					
	No increase in the maximum number of repeats may be authorised.					
	Note					
	Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:					
	(a) a nurse educator/counsellor for patients; and					
	(b) 24-hour access by patients to medical advice; and					
	(c) an established liver clinic.					
	Authority required					
	Chronic genotype 1 hepatitis C infection					
	Clinical criteria:					
	Patient must have compensated liver disease,					
	AND					
	Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,					
	AND					
	The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR					
	The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR					
	The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and in whom plasma HCV RNA is undetectable by an HCV RNA quantitative assay at week 4; OR					
	The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR					
	The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR					
	The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis; OR					
	The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and for whom the results of an HCV RNA qualitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL,					
	AND					
	The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,					
	AND					
	The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,					
	AND					
	The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max. Qty \$		
	assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,						
	AND						
	The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,						
	AND						
	The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,						
	AND						
	The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL,						
	AND						
	The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,						
	AND						
	The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.						
	Population criteria:						
	Patient must be aged 18 years or older,						
	AND						
	Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.						
	Treatment criteria:						
	Must be treated in an accredited treatment centre.						
	Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.						
	For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.						
	Note						
	No increase in the maximum quantity or number of units may be authorised.						
	Note						
	No increase in the maximum number of repeats may be authorised.						
	Note						
	Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:						
	(a) a nurse educator/counsellor for patients; and						
	(b) 24-hour access by patients to medical advice; and						
	(c) an established liver clinic.						
	Authority required						
	Chronic non-genotype 1 hepatitis C infection						
	Clinical criteria:						
	The treatment must be the sole PBS-subsidised treatment for hepatitis C,						
	AND						
	Patient must have compensated liver disease,						
	AND						
	The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,						
	AND						
	Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),						
	AND						
	Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,						
	AND						
	The treatment must be limited to a maximum duration of 48 weeks,						
	AND						
	The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.						
	Population criteria:						
	Patient must be aged 18 years or older,						

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	AND Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age. Treatment criteria: Must be treated in an accredited treatment centre. Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records. Note No increase in the maximum quantity or number of units may be authorised. Note No increase in the maximum number of repeats may be authorised. Note Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C: (a) a nurse educator/counsellor for patients; and (b) 24-hour access by patients to medical advice; and (c) an established liver clinic. Authority required Chronic non-genotype 1 hepatitis C infection Clinical criteria: The treatment must be the sole PBS-subsidised treatment for hepatitis C, AND Patient must have compensated liver disease, AND Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, AND The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C, AND The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis, AND The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, AND The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24. Population criteria: Patient must be aged 18 years or older, AND Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age. Treatment criteria: Must be treated in an accredited treatment centre. Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records. For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary. For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12. For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed. For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed. Caution Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer	
					Price for Max. Qty \$		
Caution							
Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.							
Note							
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:							
(a) a nurse educator/counsellor for patients; and							
(b) 24-hour access by patients to medical advice; and							
(c) an established liver clinic.							
6407F	peginterferon alfa-2b 120 microgram injection [4 x 120 microgram cartridges] (&) ribavirin 200 mg capsule [140 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack	2	5	..	*3538.34	Pegatron	MK
6409H	peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (&) ribavirin 200 mg capsule [140 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack	2	5	..	*4126.28	Pegatron	MK
6410J	peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (&) ribavirin 200 mg capsule [168 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack	2	5	..	*4126.28	Pegatron	MK
9634C	peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (&) ribavirin 200 mg capsule [196 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack	2	5	..	*4411.24	Pegatron	MK
6402Y	peginterferon alfa-2b 80 microgram injection [4 x 80 microgram cartridges] (&) ribavirin 200 mg capsule [140 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack	2	5	..	*2754.42	Pegatron	MK

Other immunostimulants

PLERIXAFOR

Authority required

Mobilisation of haematopoietic stem cells

Clinical criteria:

The treatment must be in combination with granulocyte-colony stimulating factor (G-CSF),

AND

Patient must have lymphoma; OR

Patient must have multiple myeloma,

AND

Patient must require autologous stem cell transplantation,

AND

Patient must have failed previous stem cell collection; OR

Patient must be undergoing chemotherapy plus G-CSF mobilisation and their peripheral blood CD34+ count is less than 10,000 per millilitre or less than 10 million per litre on the day of planned collection; OR

Patient must be undergoing chemotherapy plus G-CSF mobilisation and the first apheresis has yielded less than 1 million CD34+ cells/kg.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records.

Note

Applications for increased maximum quantities will only be authorised for patients with body weight greater than 100 kg.

10084R	plerixafor 24 mg/1.2 mL injection: subcutaneous infusion, 1 x 1.2 mL vial	1	1	..	7037.76	Mozobil	GZ

IMMUNOSUPPRESSANTS

IMMUNOSUPPRESSANTS

Selective immunosuppressants

ABATACEPT

Authority required

Severe active rheumatoid arthritis

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)					
	Clinical criteria:					
	Patient must have severe active rheumatoid arthritis,					
	AND					
	Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months,					
	AND					
	Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times,					
	AND					
	Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR					
	Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR					
	Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly,					
	AND					
	Patient must not receive more than 16 weeks of treatment under this restriction,					
	AND					
	The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.					
	Population criteria:					
	Patient must be aged 18 years or older.					
	Treatment criteria:					
	Must be treated by a rheumatologist; OR					
	Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.					
	For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.					
	If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.					
	The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.					
	The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.					
	If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.					
	The authority application must be made in writing and must include:					
	(1) a completed authority prescription form; and					
	(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and					
	(3) a signed patient acknowledgement.					
	At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 4 repeats will be authorised.					
	Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment.					
	Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty	\$	

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;

(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;

(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note

Special Pricing Arrangements apply.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty	\$	

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	failed to respond to treatment with that bDMARD.					
	(2) Swapping therapy.					
	Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.					
	Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.					
	A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.					
	Abatacept patients:					
	Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.					
	In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.					
	To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.					
	PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.					
	To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.					
	(3) Baseline measurements to determine response.					
	the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.					
	To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.					
	Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.					
	Authority required					
	Severe active rheumatoid arthritis					
	Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).					
	Clinical criteria:					
	Patient must have a documented history of severe active rheumatoid arthritis,					
	AND					
	Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy,					
	AND					
	Patient must not receive more than 16 weeks of treatment under this restriction,					
	AND					
	The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.					
	Population criteria:					
	Patient must be aged 18 years or older.					
	Treatment criteria:					
	Must be treated by a rheumatologist; OR					
	Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.					
	For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty	\$	

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 4 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to a treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alpha antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.					
	The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.					
	(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.					
	(a) Initial treatment.					
	Applications for initial treatment should be made where:					
	(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or					
	(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or					
	(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or					
	(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).					
	Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.					
	Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.					
	A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.					
	Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.					
	Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.					
	For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.					
	Abatacept patients:					
	Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.					
	Rituximab patients:					
	A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.					
	(b) Continuing treatment.					
	Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.					
	It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.					
	Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.					
	Rituximab patients:					
	A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.					
	Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.					
	(2) Swapping therapy.					
	Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.					
	Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.					
	A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.					
	Abatacept patients:					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment,

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment.

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis,

AND

Patient must have demonstrated an adequate response to treatment with this drug,

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

AND

Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction,

AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					Qty \$	

chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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	Rituximab patients:					
	A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.					
	Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.					
	(2) Swapping therapy.					
	Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.					
	Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.					
	A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.					
	Abatacept patients:					
	Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.					
	In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.					
	To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.					
	PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.					
	To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.					
	(3) Baseline measurements to determine response.					
	The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.					
	To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.					
	Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.					
	Authority required					
	Severe active rheumatoid arthritis					
	Treatment Phase: Continuing Treatment – balance of supply.					
	Clinical criteria:					
	Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment,					
	AND					
	The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.					
	Treatment criteria:					
	Must be treated by a rheumatologist; OR					
	Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.					
	Note					
	Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).					
	Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:					
	Department of Human Services					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					Price for Max. Qty \$		
	Prior Written Approval of Complex Drugs						
	Reply Paid 9826						
	GPO Box 9826						
	HOBART TAS 7001						
9621J	abatacept 250 mg injection, 1 x 250 mg vial	1	..	..	531.37	Orencia	BQ

ECULIZUMAB

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment 1 – New patient

Clinical criteria:

Patient must have active and progressing thrombotic microangiopathy (TMA),

AND

Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample taken prior to plasma exchange or infusion; or, if ADAMTS-13 activity was not collected prior to plasma exchange or infusion, patient must have platelet counts of greater than $30 \times 10^9/L$ and a serum creatinine of greater than 150 mol/L,

AND

Patient must have a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days,

AND

Patient must have clinical features of active organ damage or impairment,

AND

Patient must not receive more than 4 weeks of treatment under this restriction.

Treatment criteria:

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

Evidence of active and progressing TMA is defined by the following:

(1) a platelet count of less than $150 \times 10^9/L$; and evidence of two of the following:

- (i) presence of schistocytes on blood film;
- (ii) low or absent haptoglobin;
- (iii) lactate dehydrogenase (LDH) above normal range;

OR

(2) tissue biopsy confirming TMA in patients who don t have evidence of platelet consumption and haemolysis;

AND

(3) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:

(a) kidney impairment as demonstrated by one of the following:

- (i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or
- (ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or
- (iii) a sCr of greater than the age-appropriate ULN in paediatric patients ; or
- (iv) a renal biopsy

(b) onset of TMA-related neurological impairment;

(c) onset of TMA-related cardiac impairment;

(d) onset of TMA-related gastrointestinal impairment;

(e) onset of TMA-related pulmonary impairment

The authority application must be in writing and must include:

- (1) A completed authority prescription form; and
- (2) A completed aHUS eculizumab Authority Application Supporting Information Form- Initial PBS-subsidised eculizumab treatment; and
- (3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and
- (4) A copy of a current Certificate of vaccination; and
- (5) A measurement of body weight at the time of application; and

(6) The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion; the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the two weeks prior to collection of the ADAMTS-13 assay; and

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty \$		
	(7) In the case that a sample for ADAMTS-13 assay was not collected prior to plasma exchange or infusion, measurement of ADAMTS-13 activity must be taken 1-2 weeks following the last plasma exchange or infusion. The ADAMTS-13 result must be submitted to the Department of Human Services within 27 days of commencement of eculizumab treatment in order for the patient to be considered as eligible for further PBS-subsidised eculizumab treatment, under Initial treatment 1-balance of supply; and (8) A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days; and (9) Evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records. All tests must have been performed within one month of application; and (10) For all patients, a recent measurement of eGFR, platelets and two of either LDH, haptoglobin or schistocytes of no more than 1 week old at the time of application. <u>Note</u> Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. This will assist DHS in the consideration of the patient s eligibility for further PBS subsidised treatment <u>Note</u> At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for four weeks of treatment, according to the specified dosage in the approved Product Information (PI) <u>Note</u> Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved. <u>Note</u> WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis) > Vaccinate patients with a meningococcal vaccine at least 2 weeks prior to receiving the first dose of eculizumab; revaccinate according to current medical guidelines for vaccine use > Patients less than 2 years of age and those who are treated with eculizumab less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination. Monitor patients for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary. <u>Note</u> Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.						
10182X	eculizumab 300 mg/30 mL injection, 1 x 30 mL vial	1	..	..	5984.26		Soliris
							XI

ECULIZUMAB

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment 1 – New patient – Balance of Supply

Clinical criteria:

Patient must have received PBS-subsidised initial supply of eculizumab for this condition,

AND

Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample,

AND

Patient must not receive more than 20 weeks supply under this restriction.

Treatment criteria:

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					Price for Max. Qty \$	

ADAMTS-13 activity result must have been submitted to the Department of Human Services. In the case that a sample for ADAMTS-13 activity taken prior to plasma exchange or infusion was not available at the time of application for Initial Treatment 1 New Patient, ADAMTS-13 activity must have been measured 1-2 weeks following the last plasma exchange or infusion, and must have been submitted to the Department of Human Services within 27 days of commencement of eculizumab. The date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of the last, if any, plasma exchange or infusion that was undertaken in the two weeks prior to collection of the ADAMTS-13 assay must also have been provided to Department of Human Services.

Note

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. This will assist DHS in the consideration of the patient's eligibility for further PBS subsidised treatment

Note

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 4 repeats, according to the specified dosage in the approved Product Information (PI).

Note

Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

10192K	eculizumab 300 mg/30 mL injection, 1 x 30 mL vial	1	4	..	5984.26	Soliris	XI

ECULIZUMAB

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing treatment – New patient

Clinical criteria:

Patient must have received 24 weeks therapy under the initial restriction with PBS subsidised eculizumab for this condition,

AND

Patient must have demonstrated on-going treatment response of PBS-subsidised eculizumab treatment for this condition,

AND

Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Treatment criteria:

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
	c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.						

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure .

A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided.

The authority application must be in writing and must include:

- (1) A completed authority prescription form; and
- (2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and
- (3) A copy of a current Certificate of vaccination; and
- (4) A measurement of body weight at the time of application; and
- (5) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application ; and
- (6) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
- (7) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

Note

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).

Note

Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note

WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis)

> Vaccinate patients with a meningococcal vaccine at least 2 weeks prior to receiving the first dose of eculizumab; revaccinate according to current medical guidelines for vaccine use

> Patients less than 2 years of age and those who are treated with eculizumab less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination. Monitor patients

for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing treatment – beyond initial 48 weeks of treatment

Clinical criteria:

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	Patient must have received 48 weeks of treatment under Initial treatment-New patient, Initial treatment-Balance of supply and Continuing treatment-New patient with PBS-subsidised eculizumab for this condition,					
	AND					
	Patient must have demonstrated on-going treatment response with PBS-subsidised eculizumab for this condition,					
	AND					
	Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition,					
	AND					
	Patient must have a TMA-related cardiomyopathy as evidenced by left ventricular ejection fraction < 40%; OR					
	Patient must have severe TMA-related neurological impairment; OR					
	Patient must have severe TMA-related gastrointestinal impairment; OR					
	Patient must have severe TMA-related pulmonary impairment; OR					
	Patient must have grade 4 or 5 chronic kidney disease (eGFR of less than 30 ml/min),					
	AND					
	Patient must not receive more than 24 weeks of treatment under this restriction.					
	Treatment criteria:					
	Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.					
	A treatment response is defined as:					
	(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND					
	(2) One of the following:					
	a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or					
	b) an eGFR within +/- 25% from baseline; or					
	c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.					
	PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure . A treatment failure is defined as a patient who is:					
	(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or					
	(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.					
	Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. This will assist DHS in the consideration of the patient s eligibility for further PBS subsidised treatment.					
	The authority application must be in writing and must include:					
	(1) A completed authority prescription form; and					
	(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and					
	(3) A copy of a current Certificate of vaccination; and					
	(4) A measurement of body weight at the time of application; and					
	(5) A supporting statement with clinical evidence of severe TMA-related cardiomyopathy (including current LVEF result), neurological impairment, gastrointestinal impairment or pulmonary impairment; and					
	(6) Evidence that the patient has had a treatment response including haematological results of no more than 1 month old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 month old at the time of application; and					
	(7) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

(8) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

Note

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).

Note

Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note

WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis)

> Vaccinate patients with a meningococcal vaccine at least 2 weeks prior to receiving the first dose of eculizumab; revaccinate according to current medical guidelines for vaccine use

> Patients less than 2 years of age and those who are treated with eculizumab less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination. Monitor patients

for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment 2 – Recommencement of treatment after an initial 48-week period

Clinical criteria:

Patient must have demonstrated treatment response to previous 48 weeks of treatment with PBS-subsidised eculizumab for this condition,

AND

Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition,

AND

Patient must have the following clinical conditions: (i) either significant haemolysis as measured by low/absent haptoglobin; or presence of schistocytes on the blood film; or lactate dehydrogenase (LDH) above normal; AND (ii) either platelet consumption as measured by either 25% decline from patient baseline or thrombocytopenia (platelet count $<150 \times 10^9/L$); OR (iii) TMA-related organ impairment including on recent biopsy,

AND

Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
	c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.						

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. This will assist DHS in the consideration of the patient's eligibility for further PBS subsidised treatment.

The authority application must be in writing and must include:

- (1) A completed authority prescription form(s); and
- (2) A completed aHUS eculizumab Authority Application Supporting Information Form for Initial treatment 2- Recommencement of treatment after an initial 48-week period; and
- (3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and
- (4) A copy of a current Certificate of vaccination; and
- (5) A measurement of body weight at the time of application, and
- (6) A supporting statement with clinical evidence of TMA-related organ damage including current (within one week of application) haematological results (platelet count, haptoglobin and LDH), eGFR level, and, if applicable, on recent biopsy;
- (7) Evidence that the patient has had a treatment response to their previous treatment with eculizumab; and
- (8) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
- (9) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

Note

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).

Note

Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note

A raise in LDH alone is not a sufficient reason to re-commence eculizumab, but thrombocytopenia with one marker of haemolysis (such as raised LDH, presence of schistocytes, or low/absence of haptoglobin) is an accepted reason to consider re-commencement of eculizumab treatment.

Note

Kidney transplantation/dialysis is not a contraindication to recommencement of eculizumab treatment.

Note

WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis)

> Vaccinate patients with a meningococcal vaccine at least 2 weeks prior to receiving the first dose of eculizumab; revaccinate according to current medical guidelines for vaccine use

> Patients less than 2 years of age and those who are treated with eculizumab less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination. Monitor patients

for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing treatment – following recommencement of treatment after an initial 48-week period

Clinical criteria:

Patient must have received Initial treatment 2-recommencement of treatment after an initial 48-week period with PBS-subsidised eculizumab for this condition,

AND

Patient must have demonstrated ongoing treatment response to the previous 24 weeks of PBS-subsidised eculizumab for this condition,

AND

Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition,

AND

Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. This will assist DHS in the consideration of the patient's eligibility for further PBS subsidised treatment.

The authority application must be in writing and must include:

(1) A completed authority prescription form; and

(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and

(3) A copy of a current Certificate of vaccination; and

(4) A measurement of body weight at the time of application; and

(5) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application ; and

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

(6) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and

(7) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

Note

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).

Note

Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note

WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis)

> Vaccinate patients with a meningococcal vaccine at least 2 weeks prior to receiving the first dose of eculizumab; revaccinate according to current medical guidelines for vaccine use

> Patients less than 2 years of age and those who are treated with eculizumab less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination. Monitor patients

for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial 3 - Grandfather eculizumab patients

Clinical criteria:

Patient must have had documented history of active and progressing thrombotic microangiopathy (TMA),

AND

Patient must have had documented an ADAMTS-13 activity level consistent with a diagnosis of aHUS,

AND

Patient must have received treatment with eculizumab for this condition prior to 1 December 2014,

AND

Patient must have received treatment with eculizumab within the last 6 months at the time of application,

AND

Patient must have demonstrated on-going treatment response as specified in the Continuing treatment New Patient criteria for PBS-subsidised treatment with eculizumab for this condition, if the patient has received adequate therapy in order to demonstrate response,

AND

Patient must not have experienced treatment failure with eculizumab for this condition as specified in the Continuing treatment New Patient criteria for PBS-subsidised treatment with eculizumab for this condition,

AND

Patient must have clinical features of active organ damage or impairment at the time of a diagnosis of aHUS episode that required treatment with eculizumab,

AND

Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

Evidence of active and progressing TMA is defined by the following:

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	(1) a platelet count of less than $150 \times 10^9/L$; and evidence of two of the following: (i) presence of schistocytes on blood film; (ii) low or absent haptoglobin; (iii) lactate dehydrogenase (LDH) above normal range; OR (2) tissue biopsy confirming TMA in patients who don t have evidence of platelet consumption and haemolysis; AND (3) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below: (a) kidney impairment as demonstrated by one of the following: (i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or (ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or (iii) a sCr of greater than the age-appropriate ULN in paediatric patients ; or (iv) a renal biopsy (b) onset of TMA-related neurological impairment; (c) onset of TMA-related cardiac impairment; (d) onset of TMA-related gastrointestinal impairment; (e) onset of TMA-related pulmonary impairment A treatment response is defined as: (1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND (2) One of the following: a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or b) an eGFR within +/- 25% from baseline; or c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline. PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure . A treatment failure is defined as a patient who is: (1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or (2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented. The authority application must be in writing and must include: (1) A completed authority prescription form; and (2) A completed aHUS eculizumab Authority Application Supporting Information Form for initial PBS-subsidised eculizumab treatment; and (3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and (4) A copy of a current Certificate of vaccination; and (5) A measurement of body weight at the time of application; and (6) The result of ADAMTS-13 activity on a blood sample at the time this condition was diagnosed; and (7) Evidence that the patient has previously received treatment with eculizumab for this condition within the last 6 months at the time of application; and (8) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application ; or clinical reasons to justify the commencing of treatment with PBS-subsidised eculizumab; and (9) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
	(10) A confirmed negative STEC (Shiga toxin-producing E.Coli) result if available at the time of diagnosis; or evidence that the diagnosis was not associated with an infection; and						
	(11) Where available in the week prior to commencing eculizumab results demonstrating:						
	(a) a platelet count of less than $150 \times 10^9/L$; and evidence of two of the following:						
	(i) presence of schistocytes on blood film;						
	(ii) low or absent haptoglobin;						
	(iii) lactate dehydrogenase (LDH) above normal range;						
	OR						
	(b) tissue biopsy confirming TMA in patients who don t have evidence of platelet consumption and haemolysis;						
	AND						
	(c) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:						
	(a) kidney impairment as demonstrated by one of the following:						
	(i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or						
	(ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or						
	(iii) a sCr of greater than the age-appropriate ULN in paediatric patients ; or						
	(iv) a renal biopsy						
	(b) onset of TMA-related neurological impairment;						
	(c) onset of TMA-related cardiac impairment;						
	(d) onset of TMA-related gastrointestinal impairment;						
	(e) onset of TMA-related pulmonary impairment ; and						
	(12) Where available within one month prior to commencement of eculizumab, evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records.						

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. This will assist DHS in the consideration of the patient s eligibility for further PBS subsidised treatment.

Note

WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis)

> Vaccinate patients with a meningococcal vaccine at least 2 weeks prior to receiving the first dose of eculizumab; revaccinate according to current medical guidelines for vaccine use

> Patients less than 2 years of age and those who are treated with eculizumab less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination. Monitor patients

for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

10194M	eculizumab 300 mg/30 mL injection, 1 x 30 mL vial	1	5	..	5984.26	Soliris	XI

EVEROLIMUS

Authority required

Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required

Authority required

Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of cardiac allograft rejection. Management includes initiation, stabilisation and review of therapy as required

Caution

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer	
					Price for Max. Qty \$		
	Careful monitoring of patients is mandatory.						
9582H	everolimus 1 mg tablet, 60	4	5	..	*3891.56	Certican	NV
6459Y	everolimus 250 microgram tablet, 60	2	5	..	*506.58	Certican	NV
6460B	everolimus 500 microgram tablet, 60	2	5	..	*1006.40	Certican	NV
6461C	everolimus 750 microgram tablet, 60	4	5	..	*2930.36	Certican	NV

MYCOPHENOLATE

Authority required

Prophylaxis of renal allograft rejection

Treatment Phase: Management

Clinical criteria:

The treatment must be under the supervision and direction of a transplant unit.

Authority required

WHO Class III, IV or V lupus nephritis

Treatment Phase: Management

Clinical criteria:

The condition must be proven by biopsy.

Treatment criteria:

Must be treated by a nephrologist or in consultation with a nephrologist.

The name of the consulting nephrologist must be included in the patient medical records.

Caution

Careful monitoring of patients is mandatory.

Note

Management includes initiation, stabilisation and review of therapy as required.

6369F	mycophenolate 180 mg tablet: enteric, 120 tablets	2	5	..	*233.08	Myfortic	NV
6370G	mycophenolate 360 mg tablet: enteric, 120 tablets	2	5	..	*459.38	Myfortic	NV

MYCOPHENOLATE

Authority required

Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required

Authority required

Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of cardiac allograft rejection. Management includes initiation, stabilisation and review of therapy as required

Caution

Careful monitoring of patients is mandatory.

Note

For item codes 6208R and 1837Q, pharmaceutical benefits that have the form capsule 250 mg are equivalent for the purposes of substitution.

1837Q	mycophenolate Capsule 250 mg, 50	12	5	..	*572.56	^a Ceptolate	AF
6208R	mycophenolate mofetil 250 mg capsule, 100	6	5	..	*572.62	^a APO-Mycophenolate	TX
						^a CellCept	RO
						^a Mycophenolate Sandoz	SZ
						^a Pharmacor	CR
						Mycophenolate 250	

MYCOPHENOLATE

Authority required

Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required

Authority required

Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of cardiac allograft rejection. Management includes initiation, stabilisation and review of therapy as required

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty	Brand Name and Manufacturer	
					\$		
Caution							
Careful monitoring of patients is mandatory.							
6364Y	mycophenolate mofetil 1 g/5 mL oral liquid: powder for, 165 mL	2	5	..	*#517.97	CellCept	RO
6209T	mycophenolate mofetil 500 mg tablet, 50	6	5	..	*572.56	^a APO-Mycophenolate	TX
						^a CellCept	RO
						^a Ceptolate	AF
						^a Mycophenolate Sandoz	SZ
						^a Pharmacor	CR
						Mycophenolate 500	

NATALIZUMAB

Authority required

Initial treatment, as monotherapy, by a neurologist, of clinically definite relapsing-remitting multiple sclerosis in an ambulatory (without assistance or support) patient 18 years of age or older, who has experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years.

The diagnosis must be confirmed by magnetic resonance imaging of the brain and/or spinal cord and the date of the scan included in the authority application, unless the authority application is accompanied by written certification provided by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient

Authority required

Continuing treatment, as monotherapy, of clinically definite relapsing-remitting multiple sclerosis in a patient previously issued with an authority prescription for this drug who does not show continuing progression of disability while on treatment with this drug, and who has demonstrated compliance with, and an ability to tolerate, this therapy

Caution

Progressive multifocal leukoencephalopathy has been reported with this drug.

Note

Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.

Note

Special Pricing Arrangements apply.

9624M	natalizumab 300 mg/15 mL injection, 1 x 15 mL vial	1	5	..	1614.80	Tysabri	BD

SIROLIMUS

Authority required

Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required

Caution

Careful monitoring of patients is mandatory.

6436R	sirolimus 1 mg tablet, 100	2	5	..	*1493.42	Rapamune	PF
6437T	sirolimus 1 mg/mL oral liquid, 60 mL	2	5	..	*980.20	Rapamune	PF
6457W	sirolimus 2 mg tablet, 100	2	5	..	*2940.10	Rapamune	PF
9748C	sirolimus 500 microgram tablet, 100	2	5	..	*759.04	Rapamune	PF

Tumor necrosis factor alpha (TNF-) inhibitors

ADALIMUMAB

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

Clinical criteria:

Patient must have severe active juvenile idiopathic arthritis,

AND

Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; OR

Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months,

AND

Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; OR
- (b) at least 4 active joints from the following list:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and
- (3) an acknowledgement signed by a parent or authorised guardian.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

Note

Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	

failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis,

AND

Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle,

AND

Patient must not have failed PBS-subsidised therapy with adalimumab for this condition in the current treatment cycle,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be under 18 years of age.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with adalimumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised adalimumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	
	treatment with adalimumab.					

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					Price for Max. Qty \$	

details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply

Clinical criteria:

Patient must have received insufficient adalimumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient adalimumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment,

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

Note

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis,

AND

Patient must have demonstrated an adequate response to treatment with adalimumab,

AND

Patient must have received adalimumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
	subsidised bDMARD therapy in this treatment cycle.						

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty \$		
	It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.						
	Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.						
	Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.						
	(2) Swapping therapy.						
	Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.						
	A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.						
	To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.						
	To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.						
	(3) Baseline measurements to determine response.						
	The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.						
	(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.						
	A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.						
	(5) Withdrawal of treatment after sustained remission.						
	Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.						
	<u>Authority required</u>						
	Severe active juvenile idiopathic arthritis						
	Treatment Phase: Continuing treatment – balance of supply						
	Clinical criteria:						
	Patient must have received insufficient adalimumab therapy under the Continuing treatment restriction to complete 24 weeks treatment,						
	AND						
	The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.						
	Treatment criteria:						
	Must be treated by a rheumatologist; OR						
	Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.						
	<u>Note</u>						
	Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).						
	Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:						
	Department of Human Services						
	Prior Written Approval of Complex Drugs						
	Reply Paid 9826						
	GPO Box 9826						
	HOBART TAS 7001						
9678J	adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes	1	..	..	1676.76	Humira	VE
9680L	adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges	1	..	..	1676.76	Humira	VE
9679K	adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	1	..	..	1676.76	Humira	VE

ETANERCEPT

Authority required

Severe active juvenile idiopathic arthritis

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

Clinical criteria:

Patient must have severe active juvenile idiopathic arthritis,

AND

Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition;
OR

Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months,

AND

Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR

Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and

(3) an acknowledgement signed by a parent or authorised guardian.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

Note

Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					Price for Max.	Qty	
					\$	\$	

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis,

AND

Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle,

AND

Patient must not have failed PBS-subsidised therapy with etanercept for this condition in the current treatment cycle,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be under 18 years of age.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					Price for Max. Qty \$	

treatment. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with etanercept in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised etanercept treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

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Prior Written Approval of Complex Drugs

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Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	commence a new treatment cycle.					
	There is no limit to the number of treatment cycles a patient may undertake.					
	(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.					
	(a) Initial treatment.					
	Applications for initial treatment should be made where:					
	(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or					
	(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or					
	(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or					
	(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).					
	Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.					
	A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.					
	Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.					
	For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.					
	(b) Continuing treatment.					
	Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.					
	It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.					
	Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.					
	Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.					
	(2) Swapping therapy.					
	Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.					
	A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.					
	To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.					
	To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.					
	(3) Baseline measurements to determine response.					
	The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.					
	(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.					
	A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.					
	(5) Withdrawal of treatment after sustained remission.					
	Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.					
	Authority required					
	Severe active juvenile idiopathic arthritis					
	Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply					
	Clinical criteria:					
	Patient must have received insufficient etanercept therapy under the Initial 1 (new patient or patient recommencing treatment after break of more					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					Qty	\$	

than 12 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient etanercept therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment,

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis,

AND

Patient must have demonstrated an adequate response to treatment with etanercept,

AND

Patient must have received etanercept as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					Price for Max.	Qty	
					\$	\$	

treatment. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

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The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					Qty	\$	
	failed to respond to treatment with that bDMARD.						
	For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.						
	(b) Continuing treatment.						
	Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.						
	It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.						
	Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.						
	Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.						
	(2) Swapping therapy.						
	Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.						
	A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.						
	To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.						
	To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.						
	(3) Baseline measurements to determine response.						
	The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.						
	(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.						
	A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.						
	(5) Withdrawal of treatment after sustained remission.						
	Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.						
	<u>Authority required</u>						
	Severe active juvenile idiopathic arthritis						
	Treatment Phase: Continuing treatment – balance of supply						
	Clinical criteria:						
	Patient must have received insufficient etanercept therapy under the Continuing treatment restriction to complete 24 weeks treatment,						
	AND						
	The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.						
	Treatment criteria:						
	Must be treated by a rheumatologist; OR						
	Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.						
	<u>Note</u>						
	Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).						
	Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:						
	Department of Human Services						
	Prior Written Approval of Complex Drugs						
	Reply Paid 9826						
	GPO Box 9826						
	HOBART TAS 7001						
9641K	ETANERCEPT Injection 50 mg in 1 mL single use auto-	1	..	..	1676.77		Enbrel PF

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty	Brand Name and Manufacturer	
					\$		
9615C	injector, 4, 1 ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1	1	..	..	1676.77	Enbrel	PF
6367D	etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack	1	..	..	854.36	Enbrel	PF

INFLIXIMAB

Authority required

Acute severe ulcerative colitis

Clinical criteria:

Patient must have received an infusion of infliximab for the treatment of this condition as a hospital inpatient no more than two weeks prior to the date of the authority application,

AND

Patient must be an adult aged 18 years or older, and prior to initiation of infliximab treatment in hospital must have been experiencing six or more bloody stools per day, plus at least one of the following: (i) Temperature greater than 37.8 degrees Celsius; (ii) Pulse rate greater than 90 beats per minute; (iii) Haemoglobin less than 105 g/L; (iv) Erythrocyte sedimentation rate greater than 30 mm/h; OR

Patient must be a child aged 6 to 17 years inclusive, and prior to initiation of infliximab treatment in hospital must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) greater than or equal to 65, with the diagnosis confirmed by a gastroenterologist, or a consultant physician as specified below,

AND

Patient must have failed to achieve an adequate response to at least 72 hours treatment with intravenous corticosteroids prior to initiation of infliximab treatment in hospital.

Population criteria:

Patient must be 6 years of age or older.

Treatment criteria:

Must be treated by a gastroenterologist; OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology, or general medicine specialising in gastroenterology].

For adults aged 18 years or older, failure to achieve an adequate response to intravenous corticosteroid treatment is defined by the Oxford criteria where:

(i) If assessed on day 3, patients pass 8 or more stools per day or 3 or more stools per day with a C-reactive protein (CRP) greater than 45 mg/L

(ii) If assessed on day 7, patients pass 3 or more stools per day with visible blood.

For children aged 6 to 17 years, failure to achieve an adequate response to intravenous corticosteroids means a PUCAI score greater than 45 at 72 hours.

At the time of authority application, prescribers should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

Before administering infliximab to a child aged 6 to 17 years, the treating clinician must have consulted with a paediatric gastroenterologist or with an institution experienced in performance of paediatric colectomy. The name of the specialist or institution must be included in the patient's medical records.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records.

Note

No increase in the maximum number of repeats may be authorised.

10057H	infliximab 100 mg injection, 1 x 100 mg vial	1	1	..	788.53	Remicade	JC

INFLIXIMAB

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment (new patient)

Clinical criteria:

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more months or have intolerance necessitating permanent treatment withdrawal, AND Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, AND Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years. Population criteria: Patient must be 6 years of age or older. Treatment criteria: Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician or specialist paediatric gastroenterologist if aged between 6 to 17 years. Applications for authorisation of initial treatment must be in writing and must include: (a) a completed authority prescription form; and (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and (iii) the signed patient acknowledgement. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised. All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment. The most recent Mayo clinic, partial Mayo clinic or PUCAI score must be no more than 1 month old at the time of application. Patients who fail to achieve a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a PUCAI score less than 10 within the first 12 weeks of receiving this drug for ulcerative colitis, or have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or have failed to maintain a PUCAI score less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug. A partial Mayo clinic or PUCAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated. The patient or guardian (required if patient aged 6 to 17 years) must have signed a patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment. If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Patients may qualify for PBS-subsidised treatment under this restriction once only. Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	

GPO Box 9826

HOBART TAS 7001

Note

Special Pricing Arrangements apply.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial PBS-subsidised treatment of moderate to severe ulcerative colitis in a patient who has previously received non-PBS-subsidised therapy with this drug (grandfather)

Clinical criteria:

Patient must have been receiving treatment with this drug prior to 1 December 2014,

AND

Patient must have had a Mayo clinic score greater than or equal to 6 prior to commencing treatment with this drug; OR

Patient must have had a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores were both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo score) prior to commencing treatment with this drug; OR

Patient must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 prior to commencing treatment with this drug; OR

Patient must have a documented history of moderate to severe refractory ulcerative colitis prior to having commenced treatment with this drug where a Mayo clinic, partial Mayo clinic or PUCAI baseline assessment is not available,

AND

Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR

Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years.

Population criteria:

Patient must be 6 years of age or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a paediatrician or specialist paediatric gastroenterologist if aged between 6 to 17 years.

Applications for authorisation of initial treatment must be in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current and baseline Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition and
 - (ii) the date of commencement of this drug and
 - (iii) the signed patient acknowledgement.

The current Mayo clinic or partial Mayo clinic or PUCAI assessment must be no more than 1 month old at the time of application. The baseline assessment must be from immediately prior to commencing treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to be sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

The patient or guardian (required if patient aged 6 to 17 years) must have signed a patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Note

Where a baseline assessment is not available, please call the Department of Human Services on 1800 700 270 to discuss (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty	\$	
	Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001						
	Note Special Pricing Arrangements apply.						
	Authority required Moderate to severe ulcerative colitis Treatment Phase: Balance of supply						
	Clinical criteria: Patient must have received insufficient therapy with this drug under the Initial treatment (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at weeks 0, 2 and 6 weeks); OR Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; OR Patient must have received insufficient therapy with this drug to complete 24 weeks of treatment under the Initial PBS-subsidised treatment restriction for patients who had previously received non-PBS subsidised treatment (Grandfathered patient), AND The treatment must provide no more than the balance of up to 3 doses (new patients) or 2 repeats (Continuing patients or Grandfathered patients).						
	Population criteria: Patient must be 6 years of age or older.						
	Treatment criteria: Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician or specialist paediatric gastroenterologist if aged between 6 to 17 years.						
	Note Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written applications for authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001						
	Note Special Pricing Arrangements apply.						
	Authority required Moderate to severe ulcerative colitis Treatment Phase: Continuing treatment						
	Clinical criteria: Patient must have previously been issued with an authority prescription for this drug for this condition, AND Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years.						
	Treatment criteria: Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a						

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a paediatrician or specialist paediatric gastroenterologist if aged between 6 to 17 years.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a PUCAI score less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Note

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

Special Pricing Arrangements apply.

10184B	infliximab 100 mg injection, 1 x 100 mg vial	1	..	..	788.53	Remicade	JC

INFLIXIMAB

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have severe active rheumatoid arthritis,

AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months,

AND

Patient must have not failed previous PBS-subsidised treatment with infliximab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times,

AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly,

AND

Patient must not receive more than 22 weeks of treatment under this restriction,

AND

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	
	The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.					
	Population criteria:					
	Patient must be aged 18 years or older.					
	Treatment criteria:					
	Must be treated by a rheumatologist; OR					
	Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.					
	For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.					
	If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.					
	The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.					
	The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.					
	If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application including severity.					
	The authority application must be made in writing and must include:					
	(1) a completed authority prescription form; and					
	(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and					
	(3) a signed patient acknowledgement.					
	At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats will be authorised.					
	Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment.					
	Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.					
	Applications for a patient who has received PBS-subsidised treatment with infliximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below.					
	Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.					
	Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.					
	If a patient fails to demonstrate a response to treatment with infliximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.					
	The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:					
	an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either					
	(a) a total active joint count of at least 20 active (swollen and tender) joints; or					
	(b) at least 4 active joints from the following list of major joints:					
	(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or					
	(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).					
	The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.					
	If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.					
	Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.					

Note

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	
The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:						

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note

Special Pricing Arrangements apply.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	
	and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.					

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis,

AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy,

AND

Patient must not receive more than 22 weeks of treatment under this restriction,

AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with infliximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

If a patient fails to demonstrate a response to a treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					Qty	\$	

due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alpha antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
	Abatacept patients:						
	Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.						
	Rituximab patients:						
	A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.						
	(b) Continuing treatment.						
	Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.						
	It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.						
	Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.						
	Rituximab patients:						
	A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.						
	Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.						
	(2) Swapping therapy.						
	Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.						
	Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.						
	A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.						
	Abatacept patients:						
	Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.						
	In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.						
	To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.						
	PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.						
	To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.						
	(3) Baseline measurements to determine response.						
	The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.						
	To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.						
	Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.						

Authority required

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	Severe active rheumatoid arthritis					
	Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.					
	Clinical criteria:					
	Patient must have received insufficient infliximab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 22 weeks treatment; OR					
	Patient must have received insufficient infliximab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 22 weeks treatment,					
	AND					
	The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.					
	Treatment criteria:					
	Must be treated by a rheumatologist; OR					
	Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.					
	Note					
	Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).					
	Written application for authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment should be forwarded to:					
	Department of Human Services					
	Prior Written Approval of Complex Drugs					
	Reply Paid 9826					
	HOBART TAS 7001					
	Authority required					
	Severe active rheumatoid arthritis					
	Treatment Phase: Continuing treatment.					
	Clinical criteria:					
	Patient must have a documented history of severe active rheumatoid arthritis,					
	AND					
	Patient must have demonstrated an adequate response to treatment with infliximab,					
	AND					
	Patient must have received infliximab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment,					
	AND					
	Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction,					
	AND					
	The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.					
	Population criteria:					
	Patient must be aged 18 years or older.					
	Treatment criteria:					
	Must be treated by a rheumatologist; OR					
	Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.					
	For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.					
	An adequate response to treatment is defined as:					
	an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;					
	AND either of the following:					
	(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or					
	(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:					
	(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or					
	(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).					
	Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					Price for Max. Qty \$	

to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for single infusion at a dose of 3 mg per kg. Up to a maximum of 2 repeats will be authorised.

All applications for continuing treatment with infliximab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

If a patient fails to demonstrate a response to treatment with infliximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					Qty	\$	

that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty \$		
	(3) Baseline measurements to determine response.						
	The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. <u>Authority required</u> Severe active rheumatoid arthritis Treatment Phase: Continuing Treatment – balance of supply. Clinical criteria: Patient must have received insufficient infliximab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Treatment criteria: Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. <u>Note</u> Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001						
6397Q	infliximab 100 mg injection, 1 x 100 mg vial	1	..	..	788.53		Remicade JC

INFLIXIMAB

Authority required

Active ankylosing spondylitis

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis,

AND

Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab or infliximab in this treatment cycle,

AND

Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender,

AND

Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

Population criteria:

Patient must be an adult.

Treatment criteria:

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty	\$	
	Must be treated by a rheumatologist. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application. Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following: (i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a completed BASDAI Assessment Form; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) a signed patient acknowledgment. The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment. A maximum of 18 weeks of treatment with this drug will be approved under this criterion. At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised. Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle. Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au Authority required Ankylosing spondylitis Treatment Phase: Initial 2 (change or recommencement for all patients) Clinical criteria: Patient must have a documented history of active ankylosing spondylitis, AND Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, AND Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, AND Patient must be eligible to receive further bDMARD therapy. Population criteria: Patient must be an adult. Treatment criteria: Must be treated by a rheumatologist. Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy)						

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment. Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form. A maximum of 18 weeks of treatment with this drug will be approved under this criterion. At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised. Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle. Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 Note TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis. Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only. A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time. From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy. A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle. A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle. A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle. There is no limit to the number of treatment cycles a patient may undertake in their lifetime. (1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010. (a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or (ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2). A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

Clinical criteria:

Patient must have active, or a documented history of active, ankylosing spondylitis,

AND

Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 18 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 18 weeks treatment,

AND

The treatment must provide no more than the balance of up to 18 weeks treatment available under the above restrictions.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

Note

Authority approval for sufficient therapy to complete a maximum of 18 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 18 weeks of treatment should be forwarded to:

Department of Human Services

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 <u>Authority required</u> Ankylosing spondylitis Treatment Phase: Continuing treatment Clinical criteria: Patient must have a documented history of active ankylosing spondylitis, AND Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, AND Patient must have demonstrated an adequate response to treatment with this drug. Population criteria: Patient must be an adult. Treatment criteria: Must be treated by a rheumatologist. An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form. All measurements provided must be no more than 1 month old at the time of application. A maximum of 24 weeks of treatment with this drug will be authorised under this criterion. At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised. All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment. Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle. <u>Note</u> Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 <u>Note</u> TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis. Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.					

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.					
	From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.					
	A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.					
	Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.					
	Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.					
	A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.					
	A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.					
	There is no limit to the number of treatment cycles a patient may undertake in their lifetime.					
	(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.					
	(a) Initial treatment.					
	Applications for initial treatment should be made where:					
	(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or					
	(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or					
	(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).					
	A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.					
	Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.					
	For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.					
	(b) Continuing treatment.					
	Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.					
	It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.					
	(2) Swapping therapy.					
	Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.					
	A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.					
	To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.					
	To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.					
	(3) Baseline measurements to determine response.					
	The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.					
	For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.					
	To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.					
	(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.						
<u>Authority required</u> Ankylosing spondylitis Treatment Phase: Continuing treatment – balance of supply Clinical criteria: Patient must have a documented history of active ankylosing spondylitis, AND Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Population criteria: Patient must be an adult. Treatment criteria: Must be treated by a rheumatologist. <u>Note</u> Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001						
6448J	infliximab 100 mg injection, 1 x 100 mg vial	1	..	..	788.53	Remicade JC

INFLIXIMAB

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe active psoriatic arthritis,

AND

Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition,

AND

Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months,

AND

Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR

Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months,

AND

Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Note

Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Note

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

Clinical criteria:

Patient must have a documented history of severe active psoriatic arthritis,

AND

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle,

AND

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle,

AND

Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle,

AND

Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty	\$	

recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle. Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime. How to prescribe biological agents for the treatment of severe active psoriatic arthritis. (1) Initial treatment. Applications for initial treatment should be made where: (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and (iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2). All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply. Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent. Grandfather patients - certolizumab pegol only. For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent. Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction. (2) Continuing treatment. Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent. (3) Swapping therapy. Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not. Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing: (i) they have not received PBS-subsidised treatment with that particular biological agent previously; or (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle. To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing. (4) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.					

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
(5)	Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.					
	Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured. Authority required Severe psoriatic arthritis Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply Clinical criteria: Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 22 weeks treatment, AND The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions. Treatment criteria: Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Note Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written application for authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 Authority required Severe psoriatic arthritis Treatment Phase: Continuing treatment Clinical criteria: Patient must have a documented history of severe active psoriatic arthritis, AND Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, AND Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Population criteria: Patient must be an adult. Treatment criteria: Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement. where pain and limitation of movement are					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

Note

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

- (1) Initial treatment.

Applications for initial treatment should be made where:

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and (iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2). All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply. Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent. Grandfather patients - certolizumab pegol only. For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent. Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.					
	(2) Continuing treatment. Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.					
	(3) Swapping therapy. Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not. Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing: (i) they have not received PBS-subsidised treatment with that particular biological agent previously; or (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialed it on the PBS; and (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle. To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.					
	(4) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.					
	(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.					
	Authority required Severe psoriatic arthritis Treatment Phase: Continuing treatment - balance of supply					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					Qty \$	
Clinical criteria:						
Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment,						
AND						
The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.						
Treatment criteria:						
Must be treated by a rheumatologist; OR						
Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.						
<u>Note</u>						
Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).						
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:						
Department of Human Services						
Prior Written Approval of Complex Drugs						
Reply Paid 9826						
GPO Box 9826						
HOBART TAS 7001						
6496X	infliximab 100 mg injection, 1 x 100 mg vial	1	..	..	788.53	Remicade
						JC

INFLIXIMAB

Authority required

Initial treatment of Crohn disease in a paediatric patient.

Initial PBS-subsidised treatment by a gastroenterologist, paediatrician or consultant physician as specified in the NOTE below, of a patient aged 6 to 17 years inclusive with moderate to severe refractory Crohn disease who satisfies the following criteria:

- (a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and
- (b) whose parent or authorised guardian has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
- (c) has failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including:
 - (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period;
 - (ii) an 8 week course of enteral nutrition;
 - (iii) immunosuppressive therapy including:
 - azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
 - 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
 - methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

- (a) severity of disease activity which results in a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
- (b) The most recent PCDAI assessment must be no more than 1 month old at the time of application.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					\$	\$	

condition; and

- (ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy], or dates of enteral nutrition; and
- (iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

Authority required

Continuing treatment of Crohn disease in a patient initiated on PBS-subsidised treatment as a paediatric patient.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, paediatrician, consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

- (a) has a documented history of moderate to severe refractory Crohn disease; and
- (b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Paediatric Crohn Disease Activity Index (PCDAI) Score by at least 15 points as compared to baseline AND a total PCDAI score of 30 points or less.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.

The PCDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, a PCDAI assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

Patients who fail to demonstrate or sustain a response to treatment with infliximab for Crohn disease as specified in the criteria for continuing treatment with infliximab, will not be eligible to receive PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

Authority required

Initial PBS-subsidised treatment of Crohn disease in a paediatric patient who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, paediatrician, consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient aged 6 to 17 years inclusive who:

- (a) has a documented history of moderate to severe refractory Crohn disease and was receiving treatment with infliximab prior to 4 July 2007; and
- (b) had a Paediatric Crohn Disease Activity Index (PCDAI) Score of greater than 30 prior to commencing treatment with infliximab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and
- (c) whose parent or authorised guardian has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.	Brand Name and Manufacturer	
					Qty \$		
	restriction for continuing treatment; and						
	(d) has demonstrated or sustained an adequate response to treatment with infliximab. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).						
	NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].						
	An adequate response to infliximab treatment is defined as a reduction in Paediatric Crohn Disease Activity Index (PCDAI) Score by at least 15 points as compared to baseline AND a total PCDAI score of 30 points or less.						
	Applications for authorisation must be made in writing and must include:						
	(a) a completed authority prescription form; and						
	(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:						
	(i) the completed current and baseline Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition; and						
	(ii) the signed patient acknowledgement.						
	The current PCDAI assessment must be no more than 1 month old at the time of application. The baseline PCDAI assessment must be from immediately prior to commencing treatment with infliximab.						
	The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.						
	Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.						
	Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.						
	Patients who fail to demonstrate or sustain a response to treatment with infliximab for Crohn disease as specified in the criteria for continuing treatment with infliximab, will not be eligible to recommence PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.						
	At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.						
	Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).						
	Patients may qualify for PBS-subsidised treatment under this restriction once only						
	Note						
	Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).						
	Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au .						
	Written applications for authority to prescribe infliximab should be forwarded to:						
	Medicare Australia						
	Prior Written Approval of Specialised Drugs						
	Reply Paid 9826						
	GPO Box 9826						
	HOBART TAS 7001						
9612X	infliximab 100 mg injection, 1 x 100 mg vial	1	..	..	788.53	Remicade	JC

INFLIXIMAB

Authority required

Initial 1 (new patients)

Initial treatment of Crohn disease in a patient assessed by CDAL.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and

(b) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(c) has failed to achieve an adequate response to prior systemic therapy including:

(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					\$	\$	

(ii) immunosuppressive therapy including:

- azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
- 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
- methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

- (a) have a severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as assessed.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

The most recent CDAI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition; and
 - (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
 - (iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

Authority required

Initial 2

Change or re-commencement of treatment of Crohn disease in a patient assessed by CDAI.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:

- (a) has a documented history of severe refractory Crohn disease; and
- (b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and
- (c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF- α antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF- α antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF- α antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF- α antagonist.

Authority applications must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					\$	\$	

(www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; and

(ii) details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

Authority required

Continuing treatment of Crohn disease in a patient assessed by CDAI.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of severe refractory Crohn disease; and

(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition.

The CDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, a CDAI assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

Authority required

Initial 1

Initial treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist, or consultant physician as specified in the NOTE below of a patient who satisfies the following criteria:

(a) has confirmed Crohn disease defined by standard clinical, endoscopic and/or imaging features, including histological evidence with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and

(b) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy; and

(c) has evidence of intestinal inflammation; and

(d) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(e) has failed to achieve an adequate response to prior systemic drug therapy including:

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
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	(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and					
	(ii) immunosuppressive therapy including:					
	— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or					
	— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or					
	— methotrexate at a dose of at least 15 mg weekly for 3 or more months.					
	NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].					
	If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.					
	If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).					
	The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:					
	(a) have evidence of intestinal inflammation, including:					
	(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR					
	(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR					
	(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;					
	AND/OR					
	(b) be assessed clinically as being in a high faecal output state;					
	AND/OR					
	(c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of infliximab.					
	All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.					
	Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.					
	Applications for authorisation must be made in writing and must include:					
	(a) a completed authority prescription form; and					
	(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:					
	(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and					
	(ii) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and					
	(iii) date of the most recent clinical assessment; and					
	(iv) the signed patient acknowledgement.					
	All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.					
	A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.					
	Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.					
	The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.					
	This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.					
	It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment					

Authority required

Initial 2

Change or re-commencement of treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient or a patient with extensive small intestine disease.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					\$	\$	

- (a) has a documented history of severe refractory Crohn disease; and
- (b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and
- (c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
- (i) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criteria, if relevant; and
- (ii). details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

Authority required

Continuing treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

- (a) has a documented history of severe refractory Crohn disease with intestinal inflammation and with short gut syndrome or with an ileostomy or colostomy; and
- (b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:

- (a) improvement of intestinal inflammation as demonstrated by:
- (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR
- (ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR
- (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or
- (b) reversal of high faecal output state; or
- (c) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
- (i) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy or the date of clinical assessment.

The patient's assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					Price for Max.	Qty	
					\$	\$	

demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

Authority required

Initial 1

Initial treatment of Crohn disease in a patient with extensive small intestine disease.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:

- (a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and
- (b) has extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; and
- (c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
- (d) has failed to achieve an adequate response to prior systemic therapy including:
 - (i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
 - (ii) immunosuppressive therapy including:
 - azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
 - 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
 - methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

- (a) have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220;

AND/OR

- (b) have evidence of active intestinal inflammation, including:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR

(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;

AND/OR

- (c) be assessed clinically as being in a high faecal output state;

AND/OR

- (d) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of infliximab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					\$	\$	

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
- (i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
- (ii) (1) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; or
- (2) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the dates of assessment of the patient's condition, if relevant; and
- (iii) date of the most recent clinical assessment; and
- (iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

Authority required

Continuing treatment of Crohn disease in a patient with extensive small intestine disease.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, or consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

- (a) has a documented history of severe refractory Crohn disease with extensive intestinal inflammation affecting more than 50 cm of the small intestine; and
- (b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:

- (a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or
- (b) improvement of intestinal inflammation as demonstrated by:
- (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR
- (ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR
- (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or
- (c) reversal of high faecal output state; or
- (d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
- (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; or
- (ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy; or
- (iii) the date of clinical assessment.

All assessments must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) Authority required Initial 3 (grandfather) Initial PBS-subsidised treatment of Crohn disease in a patient assessed by CDAI who has previously received non-PBS-subsidised therapy with infliximab. Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who: (a) has a documented history of severe refractory Crohn disease and was receiving treatment with infliximab prior to 7 March 2007; and (b) had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with infliximab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and (c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and (d) has demonstrated or sustained an adequate response to treatment with infliximab. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)]. An adequate response to infliximab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following: (i) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; and (ii) the signed patient acknowledgement. The current CDAI assessment must be no more than 1 month old at the time of application. The baseline CDAI assessment must be from immediately prior to commencing treatment with infliximab. The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion. Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab. Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised. Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Patients may qualify for PBS-subsidised treatment under this restriction once only					
	Authority required Initial 3 Initial PBS-subsidised treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient, or a patient with extensive small intestine disease, who has previously received non-PBS-subsidised therapy with infliximab. Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist, of a patient who: (a) has a documented history of severe refractory Crohn disease and was receiving treatment with infliximab prior to 7 March 2007; and (b) (1) has a history of extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; or (2) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy with a documented history of intestinal inflammation; and (c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					\$	\$	

(d) has demonstrated or sustained an adequate response to treatment with infliximab according to the criteria included in the relevant continuation restriction. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

The same criteria used to determine an inadequate response to prior treatment at baseline must be used to determine response to treatment and eligibility for continuing therapy, according to the criteria included in the continuing treatment restriction.

An adequate response to infliximab treatment is defined as:

(a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or

(b) improvement of intestinal inflammation as demonstrated by:

(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR

(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR

(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or

(c) reversal of high faecal output state; or

(d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) (1) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet, where relevant, including the date of the assessment of the patient's condition; or

(2) the reports and dates of the current and baseline pathology or diagnostic imaging test(s) in order to assess response to therapy; or

(3) the date of clinical assessment(s); and

(ii) the signed patient acknowledgement.

The patient's assessment must be no more than 1 month old at the time of application. The baseline CDAI assessments must be from immediately prior to commencing treatment with infliximab. Where a baseline assessment is not available, please call Medicare Australia on 1800 700 270 to discuss.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

Note

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for adult patients with severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	From 1 August 2008, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy. A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2008 is considered to be in their first cycle as of 1 August 2008. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle. A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle. A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle. There is no limit to the number of treatment cycles a patient may undertake in their lifetime. (1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2008. (a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or (ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2). Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab. From 1 August 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist. For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course. Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. (b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply. Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist. (2) Swapping therapy. Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, evidence of intestinal inflammation), or the prior corticosteroid therapy and immunosuppressive therapy. A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					Qty \$	
	(3) Baseline measurements to determine response.					
	Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.					
	To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.					
	(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.					
	A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.					
	(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.					
	A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 9 November 2007 or infliximab prior to 7 March 2007 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.					
	A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.					
	Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.					
	'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.					
9613Y	infliximab 100 mg injection, 1 x 100 mg vial	1	..	..	788.53	Remicade
						JC

INFLIXIMAB

Authority required

Initial treatment [Initial 1, Whole body (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

- (a) have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and
- (b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
- (c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); and
- (d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:
 - (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or
 - (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or
 - (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or
 - (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

- (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)];

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					\$	\$	

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
(iii) the signed patient and prescriber acknowledgements.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

Authority required

Initial or re-Treatment [Initial 2, Whole body (Received prior biological agent under PBS)]

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

- (a) have a documented history of severe chronic plaque psoriasis; and
- (b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
- (c) have not failed PBS-subsidised therapy with infliximab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] and
 - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised infliximab treatment within this Treatment Cycle and who wish to re-commence infliximab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised infliximab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

Authority required

Continuing treatment (Whole body)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

- (a) who have a documented history of severe chronic plaque psoriasis; and
- (b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with infliximab; and
- (c) who have demonstrated an adequate response to their most recent course of treatment with infliximab.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-biological treatment baseline value for this Treatment Cycle. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following: (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet along with the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 1 month old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with infliximab. A maximum of 24 weeks of treatment with infliximab will be authorised under this restriction. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks. A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss. It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment. Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle Authority required Initial treatment [Initial 1, Face, hand, foot (New patients — No prior biological agent)] Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who: (a) have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and (b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and (c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot); and (d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks. If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au). The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application: (a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.					

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	(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.					
	(c) The most recent PASI assessment must be no more than 1 month old at the time of application.					
	Applications for authorisation must be made in writing and must include:					
	(a) a completed authority prescription form; and					
	(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:					
	(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]]; and					
	(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and					
	(iii) the signed patient and prescriber acknowledgements.					
	A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.					
	At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.					
	Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.					
	A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.					
	It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.					
	The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline					
	Authority required					
	Initial or re-Treatment [Initial 2, Face, hand, foot (Received prior biological agent under PBS)]					
	Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:					
	(a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and					
	(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and					
	(c) have not failed PBS-subsidised therapy with infliximab for the treatment of this condition in the current Treatment Cycle.					
	Applications for authorisation must be made in writing and must include:					
	(a) a completed authority prescription form; and					
	(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:					
	(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]]; and					
	(ii) details of prior biological treatment, including dosage, date and duration of treatment.					
	Applications for patients who have demonstrated a response to PBS-subsidised infliximab treatment within this Treatment Cycle and who wish to re-commence infliximab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised infliximab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.					
	A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.					
	At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.					
	Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.					
	A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.					
	It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

Authority required

Continuing treatment (Face, hand, foot)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

- (a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and
- (b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with infliximab; and
- (c) who have demonstrated an adequate response to treatment with infliximab.

An adequate response to infliximab treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

The most recent PASI assessment must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

Note

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents'

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					Qty	\$	

appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab and ustekinumab.

From 1 March 2010, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept, infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 March 2010 is considered to be in their first Cycle as of 1 March 2010.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 March 2010, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2010.

Patients must be assessed for response to each course of continuing treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 March 2010.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or
- (iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept, infliximab or ustekinumab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					Price for Max. Qty \$	
	the same Cycle.					
	Patients who commenced treatment with adalimumab prior to 1 June 2009 or ustekinumab prior to 1 March 2010 access these interchangeability arrangements in the same way as patients who have not.					
	To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.					
	To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.					
	(5) Baseline measurements to determine response.					
	Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.					
	To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.					
	(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.					
	Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.					
	Note					
	No applications for increased repeats will be authorised.					
9617E	infliximab 100 mg injection, 1 x 100 mg vial	1	..	..	788.53	Remicade JC

INFLIXIMAB

Authority required

Initial 1

Initial treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and

(b) has an externally draining enterocutaneous or rectovaginal fistula; and

(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and

(ii) a signed patient acknowledgement.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6 will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

Authority required

Initial 2

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	Change or re-commencement of treatment of complex refractory FISTULISING CROHN DISEASE. Initial PBS-subsidised treatment with infliximab of complex refractory fistulising Crohn disease by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who: (a) has a documented history of complex refractory fistulising Crohn disease; and (b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or infliximab for a draining enterocutaneous or rectovaginal fistula; and (c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle. NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)]. To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction. Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist. Authority applications must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following: (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and (ii) details of prior TNF-alfa antagonist treatment including details of date and duration of treatment. The most recent fistula assessment must be no more than 1 month old at the time of application. A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated. This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment Authority required Initial 3 (grandfather) Initial PBS-subsidised treatment of complex refractory FISTULISING CROHN DISEASE in a patient who has previously received non-PBS-subsidised therapy with infliximab. Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who satisfies the following criteria: (a) has a documented history of complex refractory fistulising Crohn disease and was receiving treatment with infliximab prior to 1 March 2010; and (b) had a draining enterocutaneous or rectovaginal fistula(e) prior to commencing treatment with infliximab; and (c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and (d) is receiving treatment with infliximab at the time of application; and (e) has demonstrated or sustained an adequate response to treatment with infliximab. NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)]. An adequate response to infliximab treatment is defined as: (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

Australia website (www.medicareaustralia.gov.au)] which includes the following:

- (i) a completed current and baseline Fistula Assessment form including the date of assessment of the patient's condition; and
- (ii) a signed patient acknowledgement.

The current fistula assessment must be no more than 1 month old at the time of application.

The baseline fistula assessment must be from immediately prior to commencing treatment with infliximab.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

Authority required

Continuing treatment of complex refractory FISTULISING CROHN DISEASE.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

- (a) has a documented history of complex refractory fistulising Crohn disease; and
- (b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:

- (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
- (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Authority applications must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The fistula assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

Note

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term 'tumour necrosis factor (TNF) alpha antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alpha antagonists at any 1 time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alpha antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alpha antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alpha antagonist treatment prior to 1 April 2011 is considered to be in their first cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alpha antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alpha antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alpha antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alpha antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alpha antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alpha antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alpha antagonist therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alpha antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alpha antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alpha antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alpha antagonist.

For second and subsequent courses of PBS-subsidised TNF-alpha antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alpha antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alpha antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alpha antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alpha antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alpha antagonist is approved, a patient may swap if eligible to the alternate TNF-alpha antagonist within the same treatment cycle.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	
	A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing. (3) Baseline measurements to determine response. Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements. (4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. (5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab. A patient who commenced treatment with adalimumab for complex refractory fistulising Crohn disease prior to 4 November 2010 or infliximab prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.					
9674E	infliximab 100 mg injection, 1 x 100 mg vial	1	..	..	788.53	Remicade
						JC

Interleukin inhibitors

TOCILIZUMAB

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years,

AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months; OR

Patient must have received no PBS-subsidised bDMARD treatment for at least 5 years if they failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) in their last treatment cycle,

AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					Price for Max.	Qty	
					\$	\$	

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle.

Note

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.	Brand Name and Manufacturer
					Qty \$	
The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:						

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

- (1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

- (a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					Qty	\$	

failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 24 months)

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years,

AND

Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle,

AND

Patient must not have failed PBS-subsidised therapy with tocilizumab for this condition in the current treatment cycle,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty	\$	

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply

Clinical criteria:

Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment,

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years,

AND

Patient must have demonstrated an adequate response to treatment with tocilizumab,

AND

Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
	to determine response.						

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.					
	There is no limit to the number of treatment cycles a patient may undertake.					
	(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.					
	(a) Initial treatment.					
	Applications for initial treatment should be made where:					
	(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or					
	(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or					
	(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or					
	(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).					
	Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.					
	A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.					
	Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.					
	For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.					
	(b) Continuing treatment.					
	Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.					
	A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.					
	It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.					
	Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.					
	Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.					
	(2) Swapping therapy.					
	Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.					
	A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.					
	To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.					
	To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.					
	(3) Baseline measurements to determine response.					
	The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.					
	(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.					
	A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.					
	<u>Authority required</u>					
	Severe active juvenile idiopathic arthritis					
	Treatment Phase: Continuing Treatment – balance of supply					
	Clinical criteria:					
	Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment,					
	AND					
	The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.					
	Treatment criteria:					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.	Brand Name and Manufacturer	
					Qty \$		
	Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.						
	Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001						
10071C	tocilizumab 200 mg/10 mL injection, 1 x 10 mL vial	1	..	..	492.65	Actemra	RO
10078K	tocilizumab 400 mg/20 mL injection, 1 x 20 mL vial	1	..	..	978.54	Actemra	RO
10073E	tocilizumab 80 mg/4 mL injection, 1 x 4 mL vial	1	..	..	201.12	Actemra	RO

TOCILIZUMAB

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

Clinical criteria:

Patient must have severe active juvenile idiopathic arthritis,

AND

Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition;
OR

Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months,

AND

Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR

Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and

(3) an acknowledgement signed by a parent or authorised guardian.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

Note

Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle. A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle. A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle. A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle. There is no limit to the number of treatment cycles a patient may undertake. (1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014. (a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2). Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy. A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course. (b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. (2) Swapping therapy. Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months. A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing. (3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement. (4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy. A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction. (5) Withdrawal of treatment after sustained remission.					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis,

AND

Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle,

AND

Patient must not have failed PBS-subsidised therapy with tocilizumab for this condition in the current treatment cycle,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be under 18 years of age.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty	\$	
	(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).						

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

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Department of Human Services

Prior Written Approval of Complex Drugs

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Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty	\$	

bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply.

Clinical criteria:

Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment,

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

Patient must have a documented history of severe active juvenile idiopathic arthritis,

AND

Patient must have demonstrated an adequate response to treatment with tocilizumab,

AND

Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
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					\$	\$	

Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer	
					Price for Max. Qty \$		
	(2) Swapping therapy.						
	Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.						
	A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.						
	To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.						
	To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.						
	(3) Baseline measurements to determine response.						
	The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.						
	(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.						
	A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.						
	(5) Withdrawal of treatment after sustained remission.						
	Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.						
	<u>Authority required</u>						
	Severe active juvenile idiopathic arthritis						
	Treatment Phase: Continuing Treatment – balance of supply						
	Clinical criteria:						
	Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment,						
	AND						
	The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.						
	Treatment criteria:						
	Must be treated by a rheumatologist; OR						
	Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.						
	<u>Note</u>						
	Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).						
	Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:						
	Department of Human Services						
	Prior Written Approval of Complex Drugs						
	Reply Paid 9826						
	GPO Box 9826						
	HOBART TAS 7001						
10079L	tocilizumab 200 mg/10 mL injection, 1 x 10 mL vial	1	..	..	492.65	Actemra	RO
10060L	tocilizumab 400 mg/20 mL injection, 1 x 20 mL vial	1	..	..	978.54	Actemra	RO
10068X	tocilizumab 80 mg/4 mL injection, 1 x 4 mL vial	1	..	..	201.12	Actemra	RO

TOCILIZUMAB

Authority required

Initial 1 (new and recommencing patients after a break of more than 12 months)

Initial treatment by a rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient under 18 years who:

(a) has been diagnosed with systemic juvenile idiopathic arthritis; AND

(b) has polyarticular course disease and either:

(i) failure to achieve an adequate response to the following treatment regimen (see (1) below for definition of failure to achieve an adequate response):

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	
	— oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids for a minimum of 3 months; or (ii) severe intolerance of, or toxicity due to, methotrexate (see (2) below for definition of severe intolerance and toxicity); OR (c) has refractory systemic symptoms, demonstrated by: — an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy; AND (d) has not received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months. (1) The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy and must be demonstrated in all patients at the time of the initial application: (a) in a patient with polyarticular course disease: (i) an active joint count of at least 20 active (swollen and tender) joints; OR (ii) at least 4 active joints from the following list: — elbow, wrist, knee and/or ankle (assessed as swollen and tender); AND/OR — shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). (b) in a patient with refractory systemic symptoms: (i) an active joint count of at least 2 active joints; AND (ii) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; AND/OR (iii) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN). (2) Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant NSAIDs on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours. Toxicity to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonia, or serious sepsis. If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, please provide details at time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of this toxicity at the time of application. The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be provided for all subsequent continuing treatment applications. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following: (i) the date of assessment of severe active systemic juvenile idiopathic arthritis; (ii) details of prior treatment including dose and duration of treatment; (iii) pathology reports detailing CRP and platelet count where appropriate; and (3) a signed patient or authorised guardian acknowledgement form. The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application. A maximum of 16 weeks of treatment will be authorised under this restriction. At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised. Where fewer than 3 repeats are requested at the time of initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 4 weeks from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab. If a patient fails to respond to 2 courses of treatment in a treatment cycle they will not be eligible to receive further PBS-subsidised tocilizumab therapy in that treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle					

Authority required

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
Initial 2 (retrial or recommencement of treatment after a break of less than 12 months)	Initial PBS-subsidised treatment by a rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient who:					
	(a) has a documented history of systemic juvenile idiopathic arthritis; AND					
	(b) has received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months; AND					
	(c) has not failed PBS-subsidised therapy with tocilizumab for this condition more than once in the current treatment cycle.					
	The authority application must be made in writing and must include:					
	(1) completed authority prescription form(s); and					
	(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:					
	(i) pathology reports detailing CRP and platelet count where appropriate.					
	Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.					
	A maximum of 16 weeks of treatment will be authorised under this restriction.					
	At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.					
	Where fewer than 3 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with tocilizumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).					
	An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria. Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with tocilizumab.					
	Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to that course of tocilizumab.					
	If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle					
	Authority required					
Initial 3 ('grandfather' patients)	Initial treatment by a rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient who:					
	(a) has a documented history of systemic juvenile idiopathic arthritis; and					
	(b) was receiving treatment with tocilizumab prior 1 November 2011; and					
	(c) has demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with tocilizumab; and					
	(d) is receiving treatment with tocilizumab at the time of application.					
	To ensure consistency in determining response, the same indices of disease severity used to establish the baseline must be provided for all subsequent continuing treatment applications.					
	The authority application must be made in writing and must include:					
	(1) completed authority prescription form(s); and					
	(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:					
	(i) pathology reports detailing CRP and platelet count where appropriate; and					
	(3) a signed patient or authorised guardian acknowledgement form.					
	The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.					
	The baseline systemic juvenile idiopathic arthritis assessment must be provided and must be from immediately prior to commencing treatment with tocilizumab. (See NOTE (3) above for definition of baseline measurements to determine response.)					
	An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.					
	Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with tocilizumab.					
	Patients are eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.					
	At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one months supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.					
	Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty	\$	

maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

A patient may only qualify for PBS-subsidised treatment under this restriction once

Authority required

Continuing treatment

Continuing treatment with tocilizumab, by a rheumatologist or under the supervision of a paediatric rheumatology treatment centre, of a patient who:

- (a) has a documented history of systemic juvenile idiopathic arthritis; AND
- (b) has demonstrated an adequate response to treatment with tocilizumab.

An adequate response to treatment is defined as:

- (a) in a patient with polyarticular course disease:
 - (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
 - (ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
 - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
- (b) in a patient with refractory systemic symptoms:
 - (i) absence of fever greater than 38 degrees Celsius in the preceding seven days; AND/OR
 - (ii) a reduction in the CRP level and platelet count by at least 30% from baseline; AND/OR
 - (iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) baseline and current pathology reports detailing CRP and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the Initial treatment restriction, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients are eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of initial application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle

Note

Any queries concerning the arrangements to prescribe tocilizumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Further prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe tocilizumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept). Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time. PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab. In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist. A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements: — a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, — a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and — once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis. For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD. (1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010. (a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2). Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab. A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks. Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course. Abatacept patients: Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application. Rituximab patients: A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate. (b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

Note

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tocilizumab for a patient who has severe active systemic juvenile idiopathic arthritis (sJIA).

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

- continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show a response to therapy, and
- fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

Once a patient has either failed or ceased to respond to 2 courses of treatment, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised tocilizumab therapy before they are eligible to receive further PBS-subsidised tocilizumab therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was stopped to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	A patient who was receiving PBS-subsidised tocilizumab treatment immediately prior to 1 May 2012 is considered to be in their first cycle as of 1 May 2012. A patient who has had a break in tocilizumab treatment of at least 12 months immediately prior to making a new application, on or after 1 May 2012, will commence a new treatment cycle. A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of less than 12 months may commence a second course of treatment within the same treatment cycle. A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle. (1) How to prescribe PBS-subsidised tocilizumab therapy after 1 May 2012. (a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised tocilizumab treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or (ii) a patient wishes to re-commence treatment with tocilizumab following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or (iii) a patient has received the first course of PBS-subsidised (initial or continuing) tocilizumab therapy in a treatment cycle and is deemed to have failed to respond or sustain a response and the treating physician wishes to trial a second course (Initial 2). Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy. A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab for that course. For second and subsequent courses of PBS-subsidised tocilizumab, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course. (b) Continuing treatment. Following the completion of an initial treatment course with tocilizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with tocilizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted tocilizumab supply. Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab. (2) Treatment cycle. Once initial treatment with PBS-subsidised tocilizumab is approved, a patient deemed to have failed to respond to the first course of treatment may have a second course without having to requalify with respect to the indices of disease severity (joint count, fever and/or CRP level and platelet count) or the prior therapy requirements, except if the patient has had a break in therapy of more than 12 months. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. (3) Baseline measurements to determine response. Medicare Australia will determine whether a response to treatment has been demonstrated based on the relevant baseline measurements of the joint count, fever and/or CRP level and platelet count submitted with the first authority application for tocilizumab. Where a patient is deemed to have failed to respond or to sustain a response to the first course of therapy in a treatment cycle, prescribers may provide new baseline measurements for the second course of treatment within that cycle. Medicare Australia will assess response according to these revised baseline measurements. If new baseline measurements are not submitted with the initial application for the second course of treatment, then those submitted with the first course will be used by Medicare Australia to assess response to the second course. (4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy. A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised tocilizumab therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction. (5) Patients 'grandfathered' onto PBS-subsidised treatment with tocilizumab. A patient who commenced treatment with tocilizumab for severe active systemic juvenile idiopathic arthritis prior to 1 November 2011 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with tocilizumab will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further applications for treatment with tocilizumab will be assessed under the continuing treatment restriction. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 12 month break in PBS-subsidised therapy' above for further details.					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					Price for Max. Qty \$		
(6) Withdrawal of treatment after sustained remission.							
Withdrawal of treatment with tocilizumab should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to Medicare Australia at the time treatment is ceased.							
<u>Note</u>							
Special Pricing Arrangements apply.							
1423X	tocilizumab 200 mg/10 mL injection, 1 x 10 mL vial	1	..	..	492.65	Actemra	RO
1464C	tocilizumab 400 mg/20 mL injection, 1 x 20 mL vial	1	..	..	978.54	Actemra	RO
1419Q	tocilizumab 80 mg/4 mL injection, 1 x 4 mL vial	1	..	..	201.12	Actemra	RO

TOCILIZUMAB

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have severe active rheumatoid arthritis,

AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months,

AND

Patient must not have failed previous PBS-subsidised treatment with tocilizumab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times,

AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					Qty	\$	

intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to demonstrate a response to treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

- (a) a total active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list of major joints:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note

Special Pricing Arrangements apply.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist. A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements: - a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, - a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and - once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis. For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD. (1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010. (a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2). Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy. Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab. A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course. Abatacept patients: Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application. Rituximab patients: A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate. (b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients: A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.					
	Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.					
	(2) Swapping therapy.					
	Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.					
	Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.					
	A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.					
	Abatacept patients:					
	Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.					
	In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.					
	To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.					
	PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.					
	To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.					
	(3) Baseline measurements to determine response.					
	the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.					
	To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.					
	Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.					
	<u>Authority required</u>					
	Severe active rheumatoid arthritis					
	Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).					
	Clinical criteria:					
	Patient must have a documented history of severe active rheumatoid arthritis,					
	AND					
	Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy,					
	AND					
	Patient must not receive more than 16 weeks of treatment under this restriction.					
	Population criteria:					
	Patient must be aged 18 years or older.					
	Treatment criteria:					
	Must be treated by a rheumatologist; OR					
	Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.					
	For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

The authority application must be made in writing and must include:

- (a) completed authority prescription form(s); and
- (b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to demonstrate a response to a treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

Special Pricing Arrangements apply.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD. (1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010. (a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2). Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy. Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab. A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course. Abatacept patients: Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application. Rituximab patients: A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate. (b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients: A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. (2) Swapping therapy. Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled. Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

Clinical criteria:

Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment,

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment.

Clinical criteria:

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	

Patient must have a documented history of severe active rheumatoid arthritis,

AND

Patient must have demonstrated an adequate response to treatment with tocilizumab,

AND

Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to demonstrate a response to treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

Clinical criteria:

Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment,

AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.	Brand Name and Manufacturer	
					Qty \$		
	Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001						
9672C	tocilizumab 200 mg/10 mL injection, 1 x 10 mL vial	1	..	..	492.65	Actemra	RO
9673D	tocilizumab 400 mg/20 mL injection, 1 x 20 mL vial	1	..	..	978.54	Actemra	RO
9671B	tocilizumab 80 mg/4 mL injection, 1 x 4 mL vial	1	..	..	201.12	Actemra	RO

Calcineurin inhibitors

CYCLOSPORIN

Authority required

Management of rejection in patients following organ or tissue transplantation, under the supervision and direction of a transplant unit.
Management includes initiation, stabilisation and review of therapy as required

Authority required

Management (which includes initiation, stabilisation and review of therapy) by dermatologists or clinical immunologists of patients with severe atopic dermatitis for whom other systemic therapies are ineffective or inappropriate

Authority required

Management (which includes initiation, stabilisation and review of therapy) by dermatologists of patients with severe psoriasis for whom other systemic therapies are ineffective or inappropriate and in whom the disease has caused significant interference with quality of life

Authority required

Management (which includes initiation, stabilisation and review of therapy) by nephrologists of patients with nephrotic syndrome in patients in whom steroids and cytostatic drugs have failed or are not tolerated or are considered inappropriate and in whom renal function is unimpaired

Authority required

Management (which includes initiation, stabilisation and review of therapy) by rheumatologists or clinical immunologists of patients with severe active rheumatoid arthritis for whom classical slow-acting anti-rheumatic agents (including methotrexate) are ineffective or inappropriate

Caution

Careful monitoring of patients is mandatory.

6232B	cyclosporin 10 mg capsule, 60	2	5	..	*85.16	Neoral 10	NV
6354K	cyclosporin 100 mg capsule, 30	4	5	..	*683.88	^a Cyclosporin Sandoz	SZ
6125J	cyclosporin 100 mg/mL oral liquid, 50 mL	4	5	..	*1309.92	^a Neoral 100 Neoral	NV NV
6352H	cyclosporin 25 mg capsule, 30	4	5	..	*166.48	^a Cyclosporin Sandoz	SZ
6353J	cyclosporin 50 mg capsule, 30	4	5	..	*339.08	^a Neoral 25 ^a Cyclosporin Sandoz	NV SZ
						^a Neoral 50	NV

CYCLOSPORIN

Authority required

For use by organ or tissue transplant recipients

Caution

Careful monitoring of patients is mandatory.

6109M	cyclosporin 50 mg/mL injection, 10 x 1 mL ampoules	1	..	..	64.86	Sandimmun	NV

TACROLIMUS

Authority required

Management of rejection in patients following organ or tissue transplantation, under the supervision and direction of a transplant unit.
Management includes initiation, stabilisation and review of therapy as required

Caution

Careful monitoring of patients is mandatory.

6216E	tacrolimus 1 mg capsule, 100	2	5	..	*617.82	^a Pharmacor Tacrolimus	CR

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer	
9682N	tacrolimus 1 mg capsule: modified release, 60 capsules	2	5	..	*373.38	a Prograf	LL
						a Tacrolimus Sandoz	SZ
						Prograf XL	LL
6217F	tacrolimus 5 mg capsule, 50	2	5	..	*1514.92	a Pharmacor Tacrolimus 5	CR
9683P	tacrolimus 5 mg capsule: modified release, 30 capsules	2	5	..	*923.38	a Prograf	LL
						a Tacrolimus Sandoz	SZ
						Prograf XL	LL
6328C	tacrolimus 500 microgram capsule, 100	2	5	..	*312.30	a Pharmacor Tacrolimus 0.5	CR
9681M	tacrolimus 500 microgram capsule: modified release, 30 capsules	2	5	..	*98.90	a Prograf	LL
						a Tacrolimus Sandoz	SZ
						Prograf XL	LL

Other immunosuppressants

LENALIDOMIDE

Authority required

Myelodysplastic syndrome

Treatment Phase: Initial treatment

Clinical criteria:

The treatment must be limited to a maximum duration of 16 weeks,

AND

Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS),

AND

Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities,

AND

Patient must be red blood cell transfusion dependent.

Classification of a patient as Low risk requires a score of 0 on the IPSS, achieved with the following combination: less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias.

Classification of a patient as Intermediate-1 requires a score of 0.5 to 1 on the IPSS, achieved with the following possible combinations:

1. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias; OR
2. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
3. less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
4. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 2/3 cytopenias; OR
5. 5%-10% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
6. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
7. less than 5% marrow blasts with poor karyotypic status (complex, greater than 3 abnormalities), and 0/1 cytopenias.

Classification of a patient as red blood cell transfusion dependent requires that:

- (i) the patient has been transfused within the last 8 weeks; and
- (ii) the patient has received at least 8 units of red blood cell in the last 6 months prior to commencing PBS-subsidised therapy with lenalidomide; and would be expected to continue this requirement without lenalidomide treatment.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Myelodysplastic Syndrome Lenalidomide Authority Application - Supporting Information Form; and
- (c) a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and
- (d) a copy of the full blood examination report; and
- (e) a copy of the pathology report detailing the cytogenetics demonstrating Low risk or Intermediate-1 disease according to the IPSS (note: using Fluorescence in Situ Hybridization (FISH) to demonstrate MDS -5q is acceptable); and
- (f) details of transfusion requirements including: (i) the date of most recent transfusion and the number of red blood cell units transfused; and (ii) the total number of red cell units transfused in the 4 and 6 months preceding the date of this application; and
- (g) a signed patient acknowledgement form.

Note

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty \$		
	Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).						
	Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au						
	Applications for authority to prescribe should be forwarded to:						
	Department of Human Services						
	Prior Written Approval of Complex Drugs						
	Reply Paid 9826						
	GPO Box 9826						
	HOBART TAS 7001						
	<u>Note</u>						
	Special Pricing Arrangements apply.						
	<u>Authority required</u>						
	Myelodysplastic syndrome						
	Treatment Phase: Continuing treatment						
	Clinical criteria:						
	Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS),						
	AND						
	Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities,						
	AND						
	Patient must have received PBS-subsidised initial therapy with lenalidomide for myelodysplastic syndrome,						
	AND						
	Patient must have achieved and maintained transfusion independence; or least a 50% reduction in red blood cell unit transfusion requirements compared with the four month period prior to commencing initial PBS-subsidised therapy with lenalidomide,						
	AND						
	Patient must not have progressive disease.						
	Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.						
	The first authority application for continuing supply must be made in writing. Subsequent authority applications for continuing supply may be made by telephone.						
	The following evidence of response must be provided at each application:						
	(i) a haemoglobin level taken within the last 4 weeks; and						
	(ii) the date of the last transfusion; and						
	(iii) a statement of the number of units of red cells transfused in the 4 months immediately preceding this application; and						
	(iv) a statement confirming that the patient has not progressed to acute myeloid leukaemia.						
	<u>Note</u>						
	Written applications for authority to prescribe should be forwarded to:						
	Department of Human Services						
	Prior Written Approval of Complex Drugs						
	Reply Paid 9826						
	GPO Box 9826						
	HOBART TAS 7001						
	<u>Note</u>						
	Subsequent authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).						
	<u>Note</u>						
	Special Pricing Arrangements apply.						
2796E	lenalidomide 10 mg capsule, 21	1	3	..	5690.09	Revlimid	CJ
2798G	lenalidomide 5 mg capsule, 21	1	3	..	5439.14	Revlimid	CJ

LENALIDOMIDE

Authority required

Multiple myeloma

Treatment Phase: Initial PBS-subsidised treatment

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	Clinical criteria: The condition must be confirmed by a histological diagnosis, AND The treatment must be as monotherapy; OR The treatment must be in combination with dexamethasone, AND Patient must have progressive disease after at least one prior therapy, AND Patient must have undergone or be ineligible for a primary stem cell transplant, AND Patient must have experienced treatment failure after a trial of at least four (4) weeks of thalidomide at a dose of at least 100 mg daily or have failed to achieve at least a minimal response after eight (8) or more weeks of thalidomide-based therapy for progressive disease, AND Patient must not be receiving concomitant PBS-subsidised bortezomib. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Thalidomide treatment failure is defined as: (1) confirmed disease progression during thalidomide treatment or within 6 months of discontinuing thalidomide treatment; or (2) severe intolerance or toxicity unresponsive to clinically appropriate dose adjustment. Severe intolerance due to thalidomide is defined as unacceptable somnolence or sedation interfering with activities of daily living. Toxicity from thalidomide is defined as peripheral neuropathy (Grade 2 or greater, interfering with function), drug-related seizures, serious Grade 3 or 4 drug-related dermatological reactions, such as Stevens-Johnson Syndrome, or other Grade 3 or 4 toxicity. Failure to achieve at least a minimal response after 8 or more weeks of thalidomide-based therapy for progressive disease is defined as: (1) less than a 25% reduction in serum or urine M protein; or (2) in oligo-secretory and non-secretory myeloma patients only, less than a 25% reduction in the difference between involved and uninvolved serum free light chain levels. If the dosing requirement for thalidomide cannot be met, the application must state the reasons why this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; details of thalidomide treatment failure; details of the basis of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response; and (3) duration of thalidomide and daily dose prescribed; and (4) a signed patient acknowledgment. To enable confirmation of eligibility for treatment, current diagnostic reports of at least one of the following must be provided: (a) the level of serum monoclonal protein; or (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or (c) the serum level of free kappa and lambda light chains; or (d) bone marrow aspirate or trephine; or (e) if present, the size and location of lytic bone lesions (not including compression fractures); or (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or (g) if present, the level of hypercalcaemia, corrected for albumin concentration. As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					Price for Max. Qty \$		
oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided. Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program. <u>Note</u> Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 <u>Note</u> Special Pricing Arrangements apply. <u>Authority required</u> Multiple myeloma Treatment Phase: Continuing PBS-subsidised treatment Clinical criteria: Patient must have previously received an authority prescription for lenalidomide, AND Patient must not have progressive disease, AND The treatment must be as monotherapy; OR The treatment must be in combination with dexamethasone. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program. <u>Note</u> Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). <u>Note</u> Written applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 <u>Note</u> Special Pricing Arrangements apply.							
9643M	lenalidomide 10 mg capsule, 21	1	..	..	5690.09	Revlimid	CJ
9644N	lenalidomide 15 mg capsule, 21	1	..	..	6628.37	Revlimid	CJ
9645P	lenalidomide 25 mg capsule, 21	1	..	..	6980.96	Revlimid	CJ

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer	
					Price for Max. Qty \$		
9642L	lenalidomide 5 mg capsule, 21	1	..	..	5439.14	Revlimid	CJ

RITUXIMAB

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have severe active rheumatoid arthritis,

AND

Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist,

AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months,

AND

Patient must not have failed previous PBS-subsidised treatment with rituximab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times,

AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly,

AND

Patient must not receive more than 2 infusions of rituximab under this restriction,

AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction 'TNF' alfa antagonist means adalimumab, certolizumab pegol, etanercept, golimumab and infliximab.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.	Brand Name and Manufacturer
					Qty \$	

- (1) completed authority prescription form(s); and
 (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
 (3) a signed patient acknowledgement.

Assessment of a patient's response to an initial course of treatment must be made at least 12 weeks after the first infusion so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services within 4 weeks of the date it was conducted. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

If a patient who fails to demonstrate a response to treatment with rituximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who fails to demonstrate a response to rituximab treatment and who qualifies to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

- (a) a total active joint count of at least 20 active (swollen and tender) joints; or
 (b) at least 4 active joints from the following list of major joints:
 (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response

Note

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
 (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
 (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note

Special Pricing Arrangements apply.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
 Prior Written Approval of Complex Drugs
 Reply Paid 9826
 HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis,

AND

Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist,

AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy,

AND

Patient must not receive more than 2 infusions of rituximab under this restriction,

AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	Patient must be aged 18 years or older. Treatment criteria: Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. For the purposes of this restriction 'TNF' alfa antagonist means adalimumab, certolizumab pegol, etanercept, golimumab and infliximab. For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab The authority application must be made in writing and must include: (a) completed authority prescription form(s); and (b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. Applications for a patient who has received PBS-subsidised treatment with rituximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised rituximab treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised rituximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response at least 12 weeks after the first infusion. This assessment must be submitted no later than 4 weeks from the date of the assessment. A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted within 4 weeks of assessment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. If a patient fails to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. If a patient fails to demonstrate a response to a treatment with rituximab and who qualify to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Note Special Pricing Arrangements apply. Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 HOBART TAS 7001 Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept). Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time. In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	failed to respond to treatment with that bDMARD.					
	(2) Swapping therapy.					
	Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.					
	Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.					
	A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.					
	Abatacept patients:					
	Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.					
	In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.					
	To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.					
	PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.					
	To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.					
	(3) Baseline measurements to determine response.					
	The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.					
	To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.					
	Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.					
	<u>Authority required</u>					
	Severe active rheumatoid arthritis					
	Treatment Phase: Continuing treatment					
	Clinical criteria:					
	Patient must have a documented history of severe active rheumatoid arthritis,					
	AND					
	Patient must have demonstrated an adequate response to treatment with this drug,					
	AND					
	Patient must have received this drug as the most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition,					
	AND					
	Patient must not receive more than 2 infusions of rituximab under this restriction,					
	AND					
	The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.					
	Population criteria:					
	Patient must be aged 18 years or older.					
	Treatment criteria:					
	Must be treated by a rheumatologist; OR					
	Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

The authority application must be made in writing and must include:

- (a) completed authority prescription form(s); and
- (b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted within 4 weeks of assessment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

If a patient fails to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

Special Pricing Arrangements apply.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
	date of the new application for treatment with a bDMARD.						
	(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.						
	(a) Initial treatment.						
	Applications for initial treatment should be made where:						
	(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or						
	(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or						
	(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or						
	(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).						
	Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.						
	Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.						
	A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.						
	Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.						
	Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.						
	For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.						
	Abatacept patients:						
	Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.						
	Rituximab patients:						
	A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.						
	(b) Continuing treatment.						
	Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.						
	It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.						
	Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.						
	Rituximab patients:						
	A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.						
	Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.						
	(2) Swapping therapy.						
	Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.						
	Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.						
	A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.						
	Abatacept patients:						
	Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.						
	In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist						

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty	Brand Name and Manufacturer	
					\$		
	treatment.						
	To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period. To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing. (3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.						
9611W	rituximab 500 mg/50 mL injection, 1 x 50 mL vial	1	..	..	2079.67	Mabthera	RO

THALIDOMIDE

Authority required

Multiple myeloma

Caution

Thalidomide is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

Note

Patients receiving thalidomide under the PBS listing must be registered in the i-access risk management program.

9684Q	thalidomide 100 mg capsule, 28	2	..	..	*1726.76	Thalomid	CJ
6469L	thalidomide 50 mg capsule, 28	4	..	..	*1726.76	Thalomid	CJ

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					Price for Max. Qty \$		

MUSCULO-SKELETAL SYSTEM

MUSCLE RELAXANTS

MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS

Other centrally acting agents

BACLOFEN

Authority required

Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity of cerebral origin

Authority required

Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity due to multiple sclerosis

Authority required

Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity due to spinal cord injury

Authority required

Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity due to spinal cord disease

6284R	baclofen 10 mg/5 mL injection: intrathecal, 1 x 5 mL ampoule	10	..	..	*1530.46	Lioresal Intrathecal	NV

DRUGS FOR TREATMENT OF BONE DISEASES

DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

Bisphosphonates

IBANDRONIC ACID

Authority required

Bone metastases from breast cancer

9619G	ibandronic acid 6 mg/6 mL injection, 1 x 6 mL vial	1	11	..	361.77	Bondronat	RO

PAMIDRONATE DISODIUM

Authority required

Hypercalcaemia of malignancy

Clinical criteria:

Patient must have a malignancy refractory to anti-neoplastic therapy.

6286W	pamidronate disodium 15 mg/5 mL injection, 1 x 5 mL vial	4	2	..	*79.40	Pamisol	HH
6288Y	pamidronate disodium 60 mg/10 mL injection, 1 x 10 mL vial	1	2	..	79.41	Pamisol	HH

PAMIDRONATE DISODIUM

Authority required

Hypercalcaemia of malignancy

Clinical criteria:

Patient must have a malignancy refractory to anti-neoplastic therapy.

Note

Pharmaceutical benefits that have the form disodium pamidronate powder for I.V. infusion 30 mg (after reconstitution) and pharmaceutical benefits that have the form disodium pamidronate concentrated injection 30 mg are equivalent for the purposes of substitution.

6279L	pamidronate disodium 30 mg injection [2 x 30 mg vials] (& inert substance diluent [2 x 10 mL ampoules], 1 pack	1	2	..	79.42 ^a	Aredia 30 mg	NV
6287X	pamidronate disodium 30 mg/10 mL injection, 1 x 10 mL vial	2	2	..	*79.42 ^a	Pamisol	HH

PAMIDRONATE DISODIUM

Authority required

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer	
					Qty	\$		
	Hypercalcaemia of malignancy							
	Clinical criteria:							
	Patient must have a malignancy refractory to anti-neoplastic therapy.							
	<u>Authority required</u>							
	Multiple myeloma							
	<u>Authority required</u>							
	Bone metastases							
	Clinical criteria:							
	The condition must be due to breast cancer.							
	<u>Note</u>							
	Pharmaceutical benefits that have the form disodium pamidronate powder for I.V. infusion 90 mg (after reconstitution) and pharmaceutical benefits that have the form disodium pamidronate concentrated injection 90 mg are equivalent for the purposes of substitution.							
6223M	pamidronate disodium 90 mg injection [1 x 90 mg vial] (&) inert substance diluent [1 x 10 mL ampoule], 1 pack	1	11	..	113.86	^a	Aredia 90 mg	NV
6289B	pamidronate disodium 90 mg/10 mL injection, 1 x 10 mL vial	1	11	..	113.86	^a	Pamisol	HH
	ZOLEDRONIC ACID							
	<u>Authority required</u>							
	Multiple myeloma							
	<u>Authority required</u>							
	Bone metastases from breast cancer							
	<u>Authority required</u>							
	Bone metastases from castration-resistant prostate cancer							
	<u>Authority required</u>							
	Treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy							
	<u>Note</u>							
	Special Pricing Arrangements apply.							
6371H	zoledronic acid 4 mg/5 mL injection, 1 x 5 mL vial	1	11	..	474.76		Zometa	NV

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					Price for Max. Qty \$		

NERVOUS SYSTEM

ANTI-PARKINSON DRUGS

DOPAMINERGIC AGENTS

Dopa and dopa derivatives

LEVODOPA + CARBIDOPA ANHYDROUS

Authority required

Management of advanced Parkinson disease in a patient with severe disabling motor fluctuations not adequately controlled by oral therapy.

Treatment must be commenced in a hospital-based movement disorder clinic

Note

Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

A positive clinical response to Duodopa administered via a temporary nasoduodenal tube should be confirmed before a permanent percutaneous endoscopic gastrostomy (PEG) tube is inserted.

9744W	levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL gel: intestinal, 7 x 100 mL bags	8	5	..	*11582.76	Duodopa	VE

Dopamine agonists

APOMORPHINE

Authority required

Parkinson disease

Clinical criteria:

Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy.

10235Q	apomorphine hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules	72	5	..	*3643.48	Apomine	HH
9607P	apomorphine hydrochloride 20 mg/2 mL injection, 5 x 2 mL ampoules	72	5	..	*7243.48	Apomine	HH
9647R	apomorphine hydrochloride 50 mg/10 mL injection: subcutaneous infusion, 5 x 10 mL syringes	36	5	..	*7054.12	Apomine PFS	HH
9640J	apomorphine hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules	36	5	..	*9050.32	Apomine	HH

PSYCHOLEPTICS

ANTIPSYCHOTICS

Diazepines, oxazepines, thiazepines and oxepines

CLOZAPINE

Authority required

Schizophrenia

Clinical criteria:

Patient must be non-responsive to other neuroleptic agents; OR

Patient must be intolerant of other neuroleptic agents.

A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

Note

Patients receiving clozapine under the PBS listing must be registered in a clozapine patient monitoring program; Novartis Clozaril Patient Monitoring System (eCPMS) or Clopineconnect.

6102E	clozapine 100 mg tablet, 100	2	..	..	*258.84	^a Clopine 100	HH
						^a Clozaril 100	NV
6418T	clozapine 200 mg tablet, 100	2	..	..	*510.92	Clopine 200	HH
6101D	clozapine 25 mg tablet, 100	2	..	..	*75.40	^a Clopine 25	HH
						^a Clozaril 25	NV
6417R	clozapine 50 mg tablet, 100	2	..	..	*141.22	Clopine 50	HH
9632Y	clozapine 50 mg/mL oral liquid, 100 mL	1	..	..	147.16	Clopine Suspension	HH

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					Price for Max.	Qty	
					\$	\$	

RESPIRATORY SYSTEM

DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

Other systemic drugs for obstructive airway diseases

OMALIZUMAB

Authority required

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment

Clinical criteria:

Patient must be under the care of the same physician for at least 12 months,

AND

Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days,

AND

Patient must have a duration of asthma of at least 1 year,

AND

Patient must have forced expiratory volume (FEV1) less than or equal to 80% predicted, documented on 3 or more occasions in the previous 12 months,

AND

Patient must have past or current evidence of atopy, documented by skin prick testing or RAST,

AND

Patient must have total serum human immunoglobulin E greater than or equal to 76 IU/mL,

AND

Patient must have signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment,

AND

Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented,

AND

Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 12 years or older.

Treatment criteria:

Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Optimised asthma therapy includes:

(i) adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (budesonide 1600 micrograms per day or fluticasone propionate 1000 micrograms per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 micrograms bd or formoterol 12 micrograms bd) for at least 12 months, unless contraindicated or not tolerated, AND

(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application.

The initial IgE assessment must be no more than 12 months old at the time of application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND

(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					Qty	\$	

days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, must be made at around 22 to 26 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form, which includes the following:
 - (i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and
 - (ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
 - (iii) the signed patient acknowledgement; and
- (c) the IgE pathology report; and
- (d) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms.

Note

The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note

For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note

It is recommended that an application for continuing treatment is submitted at the time of the 22 to 26 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

- (1) How to prescribe PBS-subsidised omalizumab therapy:

- (a) Initial treatment:

Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

- (b) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					\$	\$	

continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) and oral corticosteroid dose, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note

Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note

Special Pricing Arrangements apply.

Authority required

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 28 weeks treatment,

AND

The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Note

Authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

Special Pricing Arrangements apply.

Authority required

Uncontrolled severe allergic asthma

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe allergic asthma,

AND

Patient must have demonstrated or sustained an adequate response to treatment with this drug,

AND

Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					\$	\$	

An adequate response to omalizumab treatment is defined as:

- (a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR
- (b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline.

All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, and the assessment of oral corticosteroid dose, must be made at around 18 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form which includes details of maintenance oral corticosteroid dose; and
- (c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms.

Note

If the same physician cannot assess the patient please call the Department of Human Services on 1800 700 270.

Note

For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note

It is recommended that an application for continuing treatment is submitted at the time of the 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

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HOBART TAS 7001

Note

TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

- (1) How to prescribe PBS-subsidised omalizumab therapy:

- (a) Initial treatment:

Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

- (b) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

- (2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.	Brand Name and Manufacturer	
					Qty \$		
	of the Asthma Control Questionnaire (ACQ; 5 item version) and oral corticosteroid dose, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.						
	(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:						
	A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.						
	(4) Monitoring of patients:						
	Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.						
	<u>Note</u>						
	Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).						
	<u>Note</u>						
	Special Pricing Arrangements apply.						
	<u>Authority required</u>						
	Uncontrolled severe allergic asthma						
	Treatment Phase: Continuing treatment - balance of supply						
	Clinical criteria:						
	Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment,						
	AND						
	The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.						
	Treatment criteria:						
	Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.						
	<u>Note</u>						
	Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).						
	Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:						
	Department of Human Services						
	Prior Written Approval of Complex Drugs						
	Reply Paid 9826						
	GPO Box 9826						
	HOBART TAS 7001						
	<u>Note</u>						
	Special Pricing Arrangements apply.						
10122R	omalizumab 150 mg/mL injection, 1 x 1 mL syringe	1	..	..	433.16	Xolair	NV
10110D	omalizumab 75 mg/0.5 mL injection, 1 x 0.5 mL syringe	1	..	..	219.96	Xolair	NV

COUGH AND COLD PREPARATIONS

EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS

Mucolytics

DORNASE ALFA

Authority required

Cystic fibrosis

Clinical criteria:

Patient must have a forced vital capacity (FVC) greater than 40% predicted for age, gender and weight,

AND

Patient must have evidence of chronic suppurative lung disease (cough and sputum most days of the week, or greater than 3 respiratory tract

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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					Price for Max.	Qty	
					\$	\$	

infections of more than 2 weeks' duration in any 12 months, or objective evidence of obstructive airways disease).

Population criteria:

Patient must be 5 years of age or older.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. The prescribing of dornase alfa therapy under the HSD program is limited to such physicians. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be by a specialist physician or paediatrician in consultation with such a unit.

The measurement of lung function is to be conducted by independent (other than the treating doctor) experienced personnel at an established lung function testing laboratory, unless this is not possible because of geographical isolation.

Prior to dornase alfa therapy, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with dornase alfa at a dose of 2.5 mg daily.

FEV1 measurement (single test under conditions as above) and a global assessment of the patient involving the patient, the patient's family (in the case of paediatric patients), the treating physician(s) and an additional independent member of the cystic fibrosis treatment team must be undertaken and documented following 3 months of initial therapy.

To be eligible for continued PBS-subsidised treatment with dornase alfa following 3 months of initial treatment:

- (1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND
- (2) the patient or the patient's family (in the case of paediatric patients) must report improvement in the patient's airway clearance; AND
- (3) the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments involving the patient, the patient's family (in the case of paediatric patients), the treating physician(s) and an additional independent member of the cystic fibrosis treatment team must be undertaken and documented at six-monthly intervals to establish that all agree that dornase alfa treatment is continuing to produce worthwhile benefits. Dornase alfa therapy should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

Other aspects of treatment, such as physiotherapy, must be continued.

Where there is documented evidence that a patient already receiving dornase alfa therapy would have met the criteria for subsidy, then the patient is eligible to continue treatment under the HSD program. Where such evidence is not available, patients will need to satisfy the initiation and continuation criteria as for new patients. (Four weeks is considered a suitable wash-out period.)

Authority required

Cystic fibrosis

Clinical criteria:

Patient must have a severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring hospital admissions more frequently than 3 times per year; OR

Patient must have significant bronchiectasis on chest high resolution computed tomography scan; OR

Patient must have severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; OR

Patient must have severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy.

Population criteria:

Patient must be less than 5 years of age.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. The prescribing of dornase alfa therapy under the HSD program is limited to such physicians. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be by a specialist physician or paediatrician in consultation with such a unit.

Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented involving the patient, the patient's family, the treating physician and an additional independent member of the cystic fibrosis treatment team to establish agreement that dornase alfa treatment is continuing to produce worthwhile benefit. Treatment with dornase alfa should cease if there is not agreement of benefit, as there is always the possibility of harm from unnecessary use. Further reassessments must be undertaken and documented at six-monthly intervals.

Authority required

Cystic fibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have initiated treatment with dornase alfa at an age of less than 5 years,

AND

Patient must have undergone a comprehensive assessment, involving the patient's family, the treating physician and an additional independent member of the cystic fibrosis treatment team which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit.

Population criteria:

Patient must be 5 years of age or older.

Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with dornase alfa should cease if there is not

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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	agreement of benefit as there is always the possibility of harm from unnecessary use.						
	<u>Authority required</u>						
	Cystic fibrosis						
	Clinical criteria:						
	Patient must have initiated treatment with dornase alfa prior to 1 November 2009,						
	AND						
	Patient must have undergone a comprehensive assessment, involving the patient's family, the treating physician and an additional independent member of the cystic fibrosis treatment team which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit.						
	Population criteria:						
	Patient must be less than 5 years of age.						
	Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with dornase alfa should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.						
	<u>Note</u>						
	Dornase alfa is not PBS-subsidised for use in combination with PBS-subsidised mannitol.						
	<u>Note</u>						
	It is highly desirable that all patients be included in the national cystic fibrosis patient database.						
6120D	dornase alfa 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules	2	5	..	*2406.76		Pulmozyme RO

MANNITOL

Authority required

Cystic fibrosis

Clinical criteria:

Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information mannitol initiation dose assessment, prior to mannitol therapy. If the patient has a negative hyperresponsiveness test they may be eligible for PBS subsidised treatment with mannitol,

AND

Patient must have a forced expiratory volume in 1 second (FEV1) greater than 30% predicted for age, gender and height,

AND

Patient must be intolerant or inadequately responsive to dornase alfa,

AND

Patient must have evidence of chronic suppurative lung disease (cough and sputum most days of the week, or greater than 3 respiratory tract infections of more than 2 weeks' duration in any 12 months, or objective evidence of obstructive airways disease).

Population criteria:

Patient must be 6 years of age or older.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. The prescribing of mannitol therapy under the HSD program is limited to such physicians. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be by a specialist physician or paediatrician in consultation with such a unit.

The measurement of lung function is to be conducted by independent (other than the treating doctor) experienced personnel at an established lung function testing laboratory, unless this is not possible because of geographical isolation.

Prior to mannitol therapy, a baseline measurement of FEV1 must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.

FEV1 measurement (single test under conditions as above) and a global assessment of the patient involving the patient, the patient's family (in the case of paediatric patients), the treating physician(s) and an additional independent member of the cystic fibrosis treatment team must be undertaken and documented following 3 months of initial therapy.

To be eligible for continued PBS-subsidised treatment with mannitol following 3 months of initial treatment:

- (1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND
- (2) the patient or the patient's family (in the case of paediatric patients) must report improvement in the patient's airway clearance; AND
- (3) the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments involving the patient, the patient's family (in the case of paediatric patients), the treating physician(s) and an additional independent member of the cystic fibrosis treatment team must be undertaken and documented at six-monthly intervals to establish that all agree that mannitol treatment is continuing to produce worthwhile benefits. Mannitol therapy should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

Other aspects of treatment, such as physiotherapy, must be continued.

Where there is documented evidence that a patient already receiving mannitol therapy would have met the criteria for subsidy then the patient is

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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	eligible to continue treatment under the HSD program. Where such evidence is not available, patients will need to satisfy the initiation and continuation criteria as for new patients. (Four weeks is considered a suitable wash-out period.)					
	<u>Authority required</u>					
	Cystic fibrosis					
	Clinical criteria:					
	Patient must have initiated treatment with mannitol prior to 1 August 2012,					
	AND					
	Patient must have undergone a comprehensive assessment involving the patient's family, the treating physician and an additional independent member of the cystic fibrosis team, which documents agreement that mannitol treatment is continuing to produce a worthwhile benefit.					
	Population criteria:					
	Patient must be 6 years of age or older.					
	Further reassessments are to be undertaken and documented every 6 months. Treatment with mannitol should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.					
	<u>Note</u>					
	Mannitol is not PBS-subsidised for use in combination with PBS-subsidised dornase alfa.					
	<u>Note</u>					
	It is highly desirable that all patients be included in the national cystic fibrosis patient database.					
2008Q	MANNITOL Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers, 1	4	5	..	*1782.76	bronchitol
						XA

OTHER RESPIRATORY SYSTEM PRODUCTS

OTHER RESPIRATORY SYSTEM PRODUCTS

Other respiratory system products

IVACAFTOR

Authority required

Cystic fibrosis

Treatment Phase: Initial treatment – New patients

Clinical criteria:

Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit,

AND

Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR

Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele,

AND

Patient must not receive more than 24 weeks of treatment under this restriction,

AND

The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

Patient must be 6 years of age or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Dosage of ivacaftor must not exceed the dose of 150 mg twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of 150 mg daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, ciprofloxacin, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib verapamil.

Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin					
	Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, prednisone, rufinamide.					
	The authority application must be in writing and must include:					
	(1) a completed authority prescription form; and					
	(2) a completed Cystic Fibrosis Ivacaftor Authority Application Supporting Information Form; and					
	(3) a signed patient acknowledgement; or an acknowledgement signed by a parent or authorised guardian, if applicable; and					
	(4) a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene; and					
	(5) the result of a FEV1 measurement performed within a month prior to the date of application. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and					
	(6) evidence that the patient has either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities; and					
	(7) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and					
	(8) a copy of a sweat chloride result; and					
	(9) height and weight measurements at the time of application; and					
	(10) a baseline measurement of the number of days of hospitalisation (including hospital-in-the home) in the previous 12 months.					
	Authority required					
	Cystic fibrosis					
	Treatment Phase: Continuing treatment					
	Clinical criteria:					
	Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit,					
	AND					
	Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition,					
	AND					
	Patient must not receive more than 24 weeks of treatment under this restriction,					
	AND					
	The treatment must be given concomitantly with standard therapy for this condition.					
	Population criteria:					
	Patient must be 6 years of age or older.					
	Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.					
	Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.					
	Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation.					
	Dosage of ivacaftor must not exceed the dose of 150 mg twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.					
	Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 28 weeks.					
	Dosage of ivacaftor must not exceed the dose of 150 mg daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, ciprofloxacin, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib verapamil.					
	Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 8 weeks.					
	Ivacaftor is not PBS-subsidised for this condition as a sole therapy.					
	Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:					
	Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort					
	Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin					
	Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, prednisone, rufinamide.					
	The authority application must be in writing and must include:					
	(1) a completed authority prescription form; and					
	(2) a completed Cystic Fibrosis Ivacaftor Authority Continuing Application Supporting Information Form; and					
	(3) the result of a FEV1 measurement performed within one month prior to the date of application. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and					
	(4) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and					
	(5) a recent sweat chloride result; and					

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
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(6) height and weight measurements at the time of application; and

(7) a measurement of number of days of hospitalisation (including hospital in the home) in the previous 6 months.

Authority required

Cystic fibrosis

Treatment Phase: Initial treatment - Grandfather patients

Clinical criteria:

Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit,

AND

Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR

Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele,

AND

Patient must have received treatment with ivacaftor for this condition prior to 1 December 2014,

AND

Patient must have received treatment with ivacaftor within the last 6 months at the time of application,

AND

Patient must not receive more than 24 weeks of treatment under this restriction,

AND

The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

Patient must be 6 years of age or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Dosage of ivacaftor must not exceed the dose of 150 mg twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of 150 mg daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, ciprofloxacin, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib verapamil.

Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, prednisone, rufinamide.

The authority application must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Cystic Fibrosis Ivacaftor Application Supporting Information Form; and

(3) a signed patient acknowledgement; or an acknowledgement signed by a parent or authorised guardian, if applicable; and

(4) a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene performed prior to commencing treatment with ivacaftor; and

(5) the result of a FEV1 measurement performed prior to commencing treatment with ivacaftor for this condition; and

(6) the result of a FEV1 measurement performed within a month prior to date of application. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and

(7) evidence that the patient had either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities prior to commencing treatment with ivacaftor for this condition; and

(8) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and

(9) a copy of sweat chloride result performed prior to commencing treatment with ivacaftor for this condition; and

(10) a recent sweat chloride result prior to commencing PBS-subsidised ivacaftor; and

(11) height and weight measurements at the time of application; and

(12) height and weight measurements performed immediately prior to commencement of ivacaftor; and

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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	(13) a baseline measurement of number of days of hospitalisation (including hospital-in-the home) in the 12 months prior to commencement of ivacaftor; and					
	(14) a measurement of the number of days of hospitalisation (including hospital-in the home) in the 6 months prior to the date of application; and					
	(15) dates of prior ivacaftor therapy.					
	<u>Note</u>					
	Special Pricing Arrangements apply.					
	<u>Note</u>					
	No increase in the maximum number of repeats may be authorised.					
	<u>Note</u>					
	Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).					
	Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au					
	Applications for authority to prescribe should be forwarded to:					
	Department of Human Services					
	Prior Written Approval of Complex Drugs					
	Reply Paid 9826					
	GPO Box 9826					
	HOBART TAS 7001					
10175M	ivacaftor 150 mg tablet, 56	1	5	..	22546.76	Kalydeco
						VR

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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VARIOUS

ALL OTHER THERAPEUTIC PRODUCTS

ALL OTHER THERAPEUTIC PRODUCTS

Iron chelating agents

DEFERASIROX

Authority required

Chronic iron overload in patients with disorders of erythropoiesis

Note

Special Pricing Arrangements apply.

6499C	deferasirox 125 mg tablet: dispersible, 28	6	5	..	*1448.26	Exjade	NV
6500D	deferasirox 250 mg tablet: dispersible, 28	6	5	..	*2849.68	Exjade	NV
9600G	deferasirox 500 mg tablet: dispersible, 28	6	5	..	*5652.58	Exjade	NV

DEFERIPRONE

Authority required

Iron overload in patients with thalassaemia major who are unable to take desferrioxamine therapy

Authority required

Iron overload in patients with thalassaemia major in whom desferrioxamine therapy has proven ineffective

9638G	deferiprone 100 mg/mL oral liquid, 250 mL	5	5	..	*1173.16	Ferriprox	TX
6416Q	deferiprone 500 mg tablet, 100	6	5	..	*2750.14	Ferriprox	TX

DEFERRIOXAMINE

Authority required

Disorders of erythropoiesis associated with treatment-related chronic iron overload

6270B	desferrioxamine mesylate 2 g injection, 1 x 2 g vial	60	5	..	*1771.36	^a Hospira Pty Limited	HH
6113R	desferrioxamine mesylate 500 mg injection, 10 x 500 mg vials	40	5	^B 17.40	*1788.76	^a Desferal 2 g	NV
				..	*2921.16	^a Hospira Pty Limited	HH
				^B 238.40	*3159.56	^a Desferal 500 mg	NV

Drugs for treatment of hyperkalemia and hyperphosphatemia

LANTHANUM

Authority required

Hyperphosphataemia

Treatment Phase: Initiation and stabilisation

Clinical criteria:

The condition must not be adequately controlled by calcium,

AND

Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR

The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy,

AND

The treatment must not be used in combination with any other phosphate binding agents.

Treatment criteria:

Patient must be undergoing dialysis for chronic kidney disease.

9637F	LANTHANUM Tablet, chewable, 1000 mg (as carbonate hydrate), 90	2	5	..	*932.38	Fosrenol	ZI
9635D	LANTHANUM Tablet, chewable, 500 mg (as carbonate hydrate), 90	2	5	..	*551.24	Fosrenol	ZI
9636E	LANTHANUM Tablet, chewable, 750 mg (as carbonate hydrate), 90	2	5	..	*828.94	Fosrenol	ZI

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.	Brand Name and Manufacturer	
					Qty \$		
SEVELAMER							
<u>Authority required</u>							
Hyperphosphataemia							
Treatment Phase: Initiation and stabilisation							
Clinical criteria:							
The condition must not be adequately controlled by calcium,							
AND							
Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR							
The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy,							
AND							
The treatment must not be used in combination with any other phosphate binding agents.							
Treatment criteria:							
Patient must be undergoing dialysis for chronic kidney disease.							
9620H	sevelamer hydrochloride 800 mg tablet, 180	2	5	..	*651.56	Renagel	GZ
SUCROFERRIC OXYHYDROXIDE							
<u>Authority required</u>							
Hyperphosphataemia							
Treatment Phase: Initiation and stabilisation							
Clinical criteria:							
The condition must not be adequately controlled by calcium,							
AND							
Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR							
The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy,							
AND							
The treatment must not be used in combination with any other phosphate binding agents.							
Treatment criteria:							
Patient must be undergoing dialysis for chronic kidney disease.							
10230K	iron (as sucroferric oxyhydroxide) 500 mg tablet: chewable, 90	2	5	..	*790.36	Velphoro	FN

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

BLOOD AND BLOOD FORMING ORGANS

ANTIHEMORRHAGICS

VITAMIN K AND OTHER HEMOSTATICS

Other systemic hemostatics

ELTROMBOPAG

Authority required

Initial (new patients)

Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who is:

(1) Splenectomised and:

(a) has had an inadequate response to, or is intolerant to, corticosteroid therapy post splenectomy; and

(b) has had an inadequate response to, or is intolerant to, immunoglobulin therapy post splenectomy;

OR

(2) Not splenectomised and:

(a) has had an inadequate response, or is intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks; and

(b) has had an inadequate response, or is intolerant to, immunoglobulin therapy; and

(c) in whom splenectomy is contraindicated for medical reasons.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of initial application:

(a) a platelet count of less than or equal to 20,000 million per L;

OR

(b) a platelet count of 20-30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made in writing and must include:

(1) a completed authority prescription form,

(2) a signed patient acknowledgement,

(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)],

(4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and

(5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion

Authority required

Initial (grandfather patients)

Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with eltrombopag prior to 1 November 2011 and in whom the criteria for initial treatment can be demonstrated to have been met at the time eltrombopag was commenced.

The authority application must be made in writing and must include:

(1) a completed authority prescription form,

(2) a signed patient acknowledgement,

(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and

(4) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion

Authority required

Continuing therapy or re-initiation after a break in therapy

First period of PBS-subsidised continuing treatment or re-initiation of interrupted PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has displayed a sustained platelet response to treatment with eltrombopag during the initial period of PBS-subsidised treatment.

For the purposes of this restriction, a sustained platelet response is defined as:

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer	
					Price for Max. Qty \$		
	(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised eltrombopag, AND either of the following: (b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart; OR (c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart. Applications for the first period of continuing PBS-subsidised treatment or re-initiation of interrupted treatment must be made in writing and must include: (1) a completed authority prescription form, and (2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and (3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy). The most recent platelet count must be no more than one month old at the time of application. A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion. Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be made by telephone Authority required Second and subsequent applications for continuing therapy Continuing treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has previously received PBS-subsidised therapy with eltrombopag and who continues to display a response to treatment with eltrombopag. For the purposes of this restriction, a continuing response to treatment with eltrombopag is defined as: (a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with eltrombopag, AND either of the following: (b) a platelet count greater than or equal to 50,000 million per L OR (c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count. Platelet counts must be no more than 1 month old at the time of application. Authority applications for second and subsequent periods of continuing therapy may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) Note Eltrombopag is not PBS-subsidised as an alternative to splenectomy. Any queries concerning the arrangements to prescribe eltrombopag may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written applications for authority to prescribe eltrombopag should be forwarded to: Medicare Australia Prior Written Approval of Specialised Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au. Note Patients will be able to trial either eltrombopag and/or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with either eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs. No applications for increased repeats will be authorised. Note No applications for increased repeats will be authorised.						
5825N	eltrombopag 25 mg tablet, 28	1	5	..	1512.00	Revolade	GK
5826P	eltrombopag 50 mg tablet, 28	1	5	..	3024.00	Revolade	GK

ROMIPILOSTIM

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

Authority required

Initial (new patients)

Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who is:

(1) Splenectomised and:

(a) has had an inadequate response to, or is intolerant to, corticosteroid therapy post splenectomy; and

(b) has had an inadequate response to, or is intolerant to, immunoglobulin therapy post splenectomy;

OR

(2) Not splenectomised and:

(a) has had an inadequate response, or is intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks; and

(b) has had an inadequate response, or is intolerant to, immunoglobulin therapy; and

(c) in whom splenectomy is contraindicated for medical reasons.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of initial application:

(a) a platelet count of less than or equal to 20,000 million per L;

OR

(b) a platelet count of 20-30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made in writing and must include:

(1) a completed authority prescription form,

(2) a signed patient acknowledgement,

(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)],

(4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and

(5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

At the time of the written authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The dose (microgram/kg/week) must be provided at the time of application.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week

Authority required

Initial (grandfather patients)

Initial PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with romiplostim prior to 1 April 2011 and in whom the criteria for initial treatment can be demonstrated to have been met at the time romiplostim was commenced.

The authority application must be made in writing and must include:

(1) a completed authority prescription form,

(2) a signed patient acknowledgement,

(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and

(4) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

For patients whose dose of romiplostim had been stable for at least 4 weeks at the time of the initial application for PBS-subsidy, the medical practitioner should request sufficient number of vials based on the weight of the patient and dose (microgram/kg/week) to provide up to 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Where the patient is in the titration phase of treatment with romiplostim, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The dose (microgram/kg/week) must be provided at the time of application.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks. Authority approval will not be given for doses of higher than 10 micrograms/kg/week Authority required Continuing therapy or re-initiation after a break in therapy First period of PBS-subsidised continuing treatment or re-initiation of interrupted PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has displayed a sustained platelet response to treatment with romiplostim during the initial period of PBS-subsidised treatment. For the purposes of this restriction, a sustained platelet response is defined as: (a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised romiplostim, AND either of the following: (b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart; OR (c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart. Applications for the first period of continuing PBS-subsidised treatment or re-initiation of interrupted treatment must be made in writing and must include: (1) a completed authority prescription form, and (2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and (3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy). The most recent platelet count must be no more than one month old at the time of application. The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised. Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be made by telephone. Authority approval will not be given for doses of higher than 10 micrograms/kg/week Authority required Second and subsequent applications for continuing therapy Continuing treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has previously received PBS-subsidised therapy with romiplostim and who continues to display a response to treatment with romiplostim. For the purposes of this restriction, a continuing response to treatment with romiplostim is defined as: (a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with romiplostim, AND either of the following: (b) a platelet count greater than or equal to 50,000 million per L OR (c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count. Platelet counts must be no more than 1 month old at the time of application. Authority applications for second and subsequent periods of continuing therapy may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised. Authority approval will not be given for doses of higher than 10 micrograms/kg/week Note Romiplostim is not PBS-subsidised as an alternative to splenectomy. Any queries concerning the arrangements to prescribe romiplostim may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written applications for authority to prescribe romiplostim should be forwarded to: Medicare Australia Prior Written Approval of Specialised Drugs Reply Paid 9826 GPO Box 9826					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer	
	HOBART TAS 7001						
	Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au .						
	<u>Note</u>						
	Patients will be able to trial either eltrombopag and/or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with either eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.						
	<u>Note</u>						
	Special Pricing Arrangements apply.						
9696H	romiplostim 250 microgram injection, 1 x 250 microgram vial	1	..	..	977.50	Nplate	AN
9698K	romiplostim 500 microgram injection, 1 x 500 microgram vial	1	..	..	1955.00	Nplate	AN

ANTIANEMIC PREPARATIONS

OTHER ANTIANEMIC PREPARATIONS

Other antianemic preparations

DARBEPOETIN ALFA

Authority required (STREAMLINED)

3334

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia

5637Q	darbepoetin alfa 10 microgram/0.4 mL injection, 4 x 0.4 mL syringes	2	5	..	*356.08	Aranesp	AN
5649H	darbepoetin alfa 100 microgram/0.5 mL injection, 1 x 0.5 mL syringe	8	5	..	*2620.48	Aranesp SureClick	AN
5651K	darbepoetin alfa 100 microgram/0.5 mL injection, 4 x 0.5 mL syringes	2	5	..	*2620.50	Aranesp	AN
5650J	darbepoetin alfa 150 microgram/0.3 mL injection, 1 x 0.3 mL syringe	8	5	..	*3904.48	Aranesp SureClick	AN
5643B	darbepoetin alfa 150 microgram/0.3 mL injection, 4 x 0.3 mL syringes	2	5	..	*3904.50	Aranesp	AN
5645D	darbepoetin alfa 20 microgram/0.5 mL injection, 1 x 0.5 mL syringe	8	5	..	*670.64	Aranesp SureClick	AN
5638R	darbepoetin alfa 20 microgram/0.5 mL injection, 4 x 0.5 mL syringes	2	5	..	*670.62	Aranesp	AN
5639T	darbepoetin alfa 30 microgram/0.3 mL injection, 4 x 0.3 mL syringes	2	5	..	*917.46	Aranesp	AN
5646E	darbepoetin alfa 40 microgram/0.4 mL injection, 1 x 0.4 mL syringe	8	5	..	*1113.60	Aranesp SureClick	AN
5640W	darbepoetin alfa 40 microgram/0.4 mL injection, 4 x 0.4 mL syringes	2	5	..	*1113.60	Aranesp	AN
5641X	darbepoetin alfa 50 microgram/0.5 mL injection, 4 x 0.5 mL syringes	2	5	..	*1376.78	Aranesp	AN
5647F	darbepoetin alfa 60 microgram/0.3 mL injection, 1 x 0.3 mL syringe	8	5	..	*1616.64	Aranesp SureClick	AN
5642Y	darbepoetin alfa 60 microgram/0.3 mL injection, 4 x 0.3 mL syringes	2	5	..	*1616.66	Aranesp	AN
5648G	darbepoetin alfa 80 microgram/0.4 mL injection, 1 x 0.4 mL syringe	8	5	..	*2128.00	Aranesp SureClick	AN
5644C	darbepoetin alfa 80 microgram/0.4 mL injection, 4 x 0.4 mL syringes	2	5	..	*2128.00	Aranesp	AN

EPOETIN ALFA

Authority required (STREAMLINED)

3334

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia

5722E	epoetin alfa 10 000 international units/mL injection, 6 x 1 mL syringes	2	5	..	*1970.30	Eprex 10000	JC
5714R	epoetin alfa 1000 international units/0.5 mL injection, 6 x 0.5 mL syringes	2	5	..	*279.30	Eprex 1000	JC

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty	Brand Name and Manufacturer	
					\$		
5713Q	epoetin alfa 20 000 international units/0.5 mL injection, 6 x 0.5 mL syringes	2	5	..	*3876.00	Eprex 20,000	JC
5719B	epoetin alfa 2000 international units/0.5 mL injection, 6 x 0.5 mL syringes	2	5	..	*516.80	Eprex 2000	JC
5720C	epoetin alfa 3000 international units/0.3 mL injection, 6 x 0.3 mL syringes	2	5	..	*666.90	Eprex 3000	JC
5718Y	epoetin alfa 40 000 international units/mL injection, 1 x 1 mL syringe	2	5	..	*1254.00	Eprex 40,000	JC
5721D	epoetin alfa 4000 international units/0.4 mL injection, 6 x 0.4 mL syringes	2	5	..	*849.30	Eprex 4000	JC
5715T	epoetin alfa 5000 international units/0.5 mL injection, 6 x 0.5 mL syringes	2	5	..	*1057.34	Eprex 5000	JC
5716W	epoetin alfa 6000 international units/0.6 mL injection, 6 x 0.6 mL syringes	2	5	..	*1255.14	Eprex 6000	JC
5717X	epoetin alfa 8000 international units/0.8 mL injection, 6 x 0.8 mL syringes	2	5	..	*1627.92	Eprex 8000	JC

EPOETIN BETA

Authority required (STREAMLINED)

3334

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia

5729M	epoetin beta 10 000 international units/0.6 mL injection, 6 x 0.6 mL syringes	2	5	..	*1970.30	NeoRecormon	RO
5724G	epoetin beta 2000 international units/0.3 mL injection, 6 x 0.3 mL syringes	2	5	..	*516.80	NeoRecormon	RO
5725H	epoetin beta 3000 international units/0.3 mL injection, 6 x 0.3 mL syringes	2	5	..	*666.90	NeoRecormon	RO
5726J	epoetin beta 4000 international units/0.3 mL injection, 6 x 0.3 mL syringes	2	5	..	*849.30	NeoRecormon	RO
5727K	epoetin beta 5000 international units/0.3 mL injection, 6 x 0.3 mL syringes	2	5	..	*1057.36	NeoRecormon	RO
5728L	epoetin beta 6000 international units/0.3 mL injection, 6 x 0.3 mL syringes	2	5	..	*1255.14	NeoRecormon	RO

EPOETIN LAMBDA

Authority required (STREAMLINED)

3334

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia

Note

Epoetin lambda should only be administered by the intravenous route.

9596C	epoetin lambda 10 000 international units/mL injection, 6 x 1 mL syringes	2	5	..	*1866.60	Novicrit	SZ
9668W	epoetin lambda 1000 international units/0.5 mL injection, 6 x 0.5 mL syringes	2	5	..	*264.60	Novicrit	SZ
9669X	epoetin lambda 2000 international units/mL injection, 6 x 1 mL syringes	2	5	..	*489.60	Novicrit	SZ
9670Y	epoetin lambda 3000 international units/0.3 mL injection, 6 x 0.3 mL syringes	2	5	..	*631.80	Novicrit	SZ
9587N	epoetin lambda 4000 international units/0.4 mL injection, 6 x 0.4 mL syringes	2	5	..	*804.60	Novicrit	SZ
9589Q	epoetin lambda 5000 international units/0.5 mL injection, 6 x 0.5 mL syringes	2	5	..	*1001.70	Novicrit	SZ
9591T	epoetin lambda 6000 international units/0.6 mL injection, 6 x 0.6 mL syringes	2	5	..	*1189.08	Novicrit	SZ
9594Y	epoetin lambda 8000 international units/0.8 mL injection, 6 x 0.8 mL syringes	2	5	..	*1542.24	Novicrit	SZ

METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA

Authority required (STREAMLINED)

3334

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty	Brand Name and Manufacturer	
					\$		
5797D	methoxy polyethylene glycol-epoetin beta 100 microgram/0.3 mL injection, 1 x 0.3 mL syringe	2	5	..	*1158.82	Mircera	RO
5798E	methoxy polyethylene glycol-epoetin beta 120 microgram/0.3 mL injection, 1 x 0.3 mL syringe	2	5	..	*1341.64	Mircera	RO
5799F	methoxy polyethylene glycol-epoetin beta 200 microgram/0.3 mL injection, 1 x 0.3 mL syringe	2	5	..	*1924.30	Mircera	RO
5794Y	methoxy polyethylene glycol-epoetin beta 30 microgram/0.3 mL injection, 1 x 0.3 mL syringe	2	5	..	*369.18	Mircera	RO
5800G	methoxy polyethylene glycol-epoetin beta 360 microgram/0.6 mL injection, 1 x 0.6 mL syringe	2	5	..	*3326.52	Mircera	RO
5795B	methoxy polyethylene glycol-epoetin beta 50 microgram/0.3 mL injection, 1 x 0.3 mL syringe	2	5	..	*615.30	Mircera	RO
5796C	methoxy polyethylene glycol-epoetin beta 75 microgram/0.3 mL injection, 1 x 0.3 mL syringe	2	5	..	*896.02	Mircera	RO

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

CARDIOVASCULAR SYSTEM

ANTIHYPERTENSIVES

OTHER ANTIHYPERTENSIVES

Other antihypertensives

AMBRISANTAN

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease,

AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds,

AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
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					\$	\$	

conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH; OR

Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease,

AND

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgement. Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. Test requirements to establish baseline for initiation of treatment are as follows: The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements. Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats may be requested. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan. Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals. Authority required Pulmonary arterial hypertension (PAH)					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
- (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note

Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	

GPO Box 9826

HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition,

AND

The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

Note

Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (all patients)

Clinical criteria:

Patient must have received approval for initial PBS-subsidised treatment with this agent,

AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					Price for Max. Qty \$		
	(6) ECHO composite assessment only.						
	The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application. Response to a PAH agent is defined as follows: For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats will be authorised. The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician. Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.						
	Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.						
	Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001						
	Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.						
5608E	ambrisentan 10 mg tablet, 30	1	..	..	2876.47	Volibris	GK
5607D	ambrisentan 5 mg tablet, 30	1	..	..	2876.47	Volibris	GK

BOSENTAN

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	AND Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH; OR Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, AND Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, AND Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include: (1) two completed authority prescription forms; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgement. Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. Test requirements to establish baseline for initiation of treatment are as follows: The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements. Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application. Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application. Response to prior vasodilator treatment is defined as follows: For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					Price for Max.	Qty	
					\$	\$	

based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH; OR

Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR

Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology),

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

- (i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6 Minute Walk Test (6MWT); and
(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) two completed authority prescription forms; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
- (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note

Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.					
	Note Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing. Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals. Authority required Pulmonary arterial hypertension (PAH) Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply Clinical criteria: Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment, AND The treatment must be the sole PBS-subsidised PAH agent for this condition, AND The treatment must provide no more than the balance of up to six months treatment available under the above restrictions. Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written applications for authorisation under this criterion should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 Authority required Pulmonary arterial hypertension (PAH) Treatment Phase: Continuing treatment (all patients) Clinical criteria: Patient must have received approval for initial PBS-subsidised treatment with this agent, AND Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent, AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include:					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					Price for Max.	Qty	
					\$	\$	

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
- (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Caution

This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					Price for Max.	Qty	
					\$	\$	
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.							
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BOSENTAN

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease,

AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds,

AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					\$	\$	

has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					Price for Max.	Qty	
	assessed by ECHO where a RHC cannot be performed on clinical grounds; OR						
	Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH; OR						
	Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR						
	Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology),						
	AND						
	The treatment must be the sole PBS-subsidised PAH agent for this condition.						
	Applications for authorisation must be in writing and must include:						
	(1) two completed authority prescription forms; and						
	(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:						
	(i) RHC composite assessment; and						
	(ii) ECHO composite assessment; and						
	(iii) 6 Minute Walk Test (6MWT); and						
	(3) a signed patient acknowledgement.						
	Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:						
	(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or						
	(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.						
	Test requirements to establish baseline for initiation of treatment are as follows:						
	The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.						
	Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:						
	(1) RHC plus ECHO composite assessments;						
	(2) RHC composite assessment plus 6MWT;						
	(3) RHC composite assessment only.						
	In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:						
	(1) ECHO composite assessment plus 6MWT;						
	(2) ECHO composite assessment only.						
	Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.						
	The test results provided must not be more than 2 months old at the time of application.						
	Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.						
	The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.						
	The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.						
	Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.						
	PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.						
	Note						
	Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.						
	The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.						

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					\$	\$	

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) two completed authority prescription forms; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
- (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty	\$	

patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note

Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

Note

Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition,

AND

The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

Note

Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (all patients)

Clinical criteria:

Patient must have received approval for initial PBS-subsidised treatment with this agent,

AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty	\$	
	Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals. Authority required Pulmonary arterial hypertension (PAH) Treatment Phase: Cessation of treatment (all patients) Clinical criteria: Patient must have received approval for initial PBS-subsidised treatment with this agent, AND Patient must have not responded to prior PBS-subsidised therapy with this agent, AND The treatment must be for the purpose of gradual dose reduction prior to ceasing therapy, AND The treatment must be the sole PBS-subsidised PAH agent for this condition. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment. Treatment beyond 1 month will not be approved. Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy. Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written applications for authorisation under this criterion should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001						
5618Q	bosentan 62.5 mg tablet, 60	1	..	..	2876.47		Tracleer AT

EPOPROSTENOL

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH; OR

Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					Price for Max.	Qty	
					\$	\$	

- (i) RHC composite assessment; and
- (ii) ECHO composite assessment; and
- (iii) 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note

Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 1.5 mg (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 1.5 mg injection vial are equivalent for the purposes of substitution.

Note

Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 500 micrograms (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 500 microgram injection vial are equivalent for the purposes of substitution.

Authority required

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change or re-commencement of therapy for all patients)

Clinical criteria:

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and must have received prior treatment with a PBS-subsidised PAH agent other than this agent; OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and must have failed to respond to a prior PBS-subsidised PAH agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
- (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and
- (4) for WHO Functional Class III patients, where this is the first application for this agent, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note

Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
	Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001						
	Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.						
	Note Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 1.5 mg (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 1.5 mg injection vial are equivalent for the purposes of substitution.						
	Note Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 500 micrograms (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 500 microgram injection vial are equivalent for the purposes of substitution.						
	Authority required Pulmonary arterial hypertension (PAH) Treatment Phase: Initial 1 (new patients) or Initial 2 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply Clinical criteria: Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the Initial 2 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment, AND The treatment must be the sole PBS-subsidised PAH agent for this condition, AND The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.						
	Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written applications for authorisation under this criterion should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001						
	Note Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 1.5 mg (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 1.5 mg injection vial are equivalent for the purposes of substitution.						
	Note Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 500 micrograms (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 500 microgram injection vial are equivalent for the purposes of substitution.						
	Authority required Pulmonary arterial hypertension (PAH) Treatment Phase: Continuing treatment (all patients) Clinical criteria: Patient must have received approval for initial PBS-subsidised treatment with this agent, AND Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent, AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include:						

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					Price for Max.	Qty	
					\$	\$	

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
- (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note

Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 1.5 mg (base) infusion administration set and

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer	
					Qty \$			
pharmaceutical benefits that have the form epoprostenol 1.5 mg injection vial are equivalent for the purposes of substitution.								
<u>Note</u>								
Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 500 micrograms (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 500 microgram injection vial are equivalent for the purposes of substitution.								
5035B	EPOPROSTENOL SODIUM Powder for I.V. infusion 1.5 mg (base) infusion administration set, 1	1	..	..	66.55	^a	Flolan Kit	GK
5030R	EPOPROSTENOL SODIUM Powder for I.V. infusion 500 micrograms (base) infusion administration set, 1	1	..	..	33.28	^a	Flolan Kit	GK
10117L	epoprostenol 1.5 mg injection, 1 x 1.5 mg vial	1	..	..	66.55	^a	Veletri	AT
10130E	epoprostenol 500 microgram injection, 1 x 500 microgram vial	1	..	..	33.28	^a	Veletri	AT

ILOPROST

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with this agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III drug-induced PAH,

AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds,

AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty	\$	

following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note

Special Pricing Arrangements apply.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III drug-induced PAH and a mean right atrial pressure greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III drug-induced PAH with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH; OR

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR Patient must have WHO Functional Class IV drug-induced PAH,					
	AND					
	The treatment must be the sole PBS-subsidised PAH agent for this condition.					
	Applications for authorisation must be in writing and must include:					
	(1) a completed authority prescription form; and					
	(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:					
	(i) RHC composite assessment; and					
	(ii) ECHO composite assessment; and					
	(iii) 6 Minute Walk Test (6MWT); and					
	(3) a signed patient acknowledgement.					
	Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:					
	(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or					
	(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.					
	Test requirements to establish baseline for initiation of treatment are as follows:					
	The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.					
	Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:					
	(1) RHC plus ECHO composite assessments;					
	(2) RHC composite assessment plus 6MWT;					
	(3) RHC composite assessment only.					
	In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:					
	(1) ECHO composite assessment plus 6MWT;					
	(2) ECHO composite assessment only.					
	Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.					
	The test results provided must not be more than 2 months old at the time of application.					
	The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.					
	A maximum of 5 repeats may be requested.					
	The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.					
	Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.					
	PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.					
	Note					
	Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).					
	Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au					
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	Department of Human Services					
	Prior Written Approval of Complex Drugs					
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HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note

Special Pricing Arrangements apply.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease or drug-induced PAH and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and must have received prior treatment with a PBS-subsidised PAH agent other than this agent; OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and must have failed to respond to a prior PBS-subsidised PAH agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
- (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and
- (4) for WHO Functional Class III patients, where this is the first application for this agent, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note

Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	
	<u>Note</u> Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 <u>Note</u> Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals. <u>Note</u> Special Pricing Arrangements apply. <u>Authority required</u> Pulmonary arterial hypertension (PAH) Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply Clinical criteria: Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment, AND The treatment must be the sole PBS-subsidised PAH agent for this condition, AND The treatment must provide no more than the balance of up to six months treatment available under the above restrictions. <u>Note</u> Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written applications for authorisation under this criterion should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 <u>Note</u> Special Pricing Arrangements apply. <u>Authority required</u> Pulmonary arterial hypertension (PAH) Treatment Phase: Continuing treatment (all patients) Clinical criteria: Patient must have received approval for initial PBS-subsidised treatment with this agent, AND Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent, AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include:					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty	\$	

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
- (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note

Special Pricing Arrangements apply.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer	
					Price for Max. Qty \$		
5751Q	iloprost 20 microgram/2 mL inhalation: solution, 30 x 2 mL ampoules	1	..	..	1076.00	Ventavis	BN

MACITENTAN

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease,

AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds,

AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH; OR

Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR

Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology),

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

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Note

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Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application. Response to a PAH agent is defined as follows: For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats may be requested. Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing. Note Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing. Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition,

AND

The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

Note

Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (all patients)

Clinical criteria:

Patient must have received approval for initial PBS-subsidised treatment with this agent,

AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer	
					Qty \$			
	The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application. Response to a PAH agent is defined as follows: For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats will be authorised. The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician. Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent. The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy. Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.							
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Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease,

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	AND					
	Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR					
	Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds,					
	AND					
	Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists,					
	AND					
	The treatment must be the sole PBS-subsidised PAH agent for this condition.					
	Applications for authorisation must be in writing and must include:					
	(1) a completed authority prescription form; and					
	(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:					
	(i) RHC composite assessment; and					
	(ii) ECHO composite assessment; and					
	(iii) 6 Minute Walk Test (6MWT); and					
	(3) a signed patient acknowledgement.					
	Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:					
	(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or					
	(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.					
	Test requirements to establish baseline for initiation of treatment are as follows:					
	The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.					
	Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:					
	(1) RHC plus ECHO composite assessments;					
	(2) RHC composite assessment plus 6MWT;					
	(3) RHC composite assessment only.					
	In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:					
	(1) ECHO composite assessment plus 6MWT;					
	(2) ECHO composite assessment only.					
	Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.					
	The test results provided must not be more than 2 months old at the time of application.					
	Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.					
	Response to prior vasodilator treatment is defined as follows:					
	For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.					
	For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.					
	For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.					
	For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.					
	The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.					
	A maximum of 5 repeats may be requested.					
	Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty	\$	

PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty	\$	

order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
- (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note

Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

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HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition,

AND

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

Note

Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (all patients)

Clinical criteria:

Patient must have received approval for initial PBS-subsidised treatment with this agent,

AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty \$		
continuity for those patients who respond to treatment, as assessed by the treating physician.							
Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.							
The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.							
PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.							
<u>Note</u>							
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).							
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au							
Applications for authority to prescribe should be forwarded to:							
Department of Human Services							
Prior Written Approval of Complex Drugs							
Reply Paid 9826							
GPO Box 9826							
HOBART TAS 7001							
<u>Note</u>							
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.							
9547L	sildenafil 20 mg tablet, 90	1	..	..	754.68	^a	APO-Sildenafil PHT TX
						^a	Revatio PF
						^a	Sildenafil AN PHT 20 EA
						^a	SILDENAFIL-DRx RZ
						^a	Sildenafil Sandoz PHT SZ

20

TADALAFIL

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease,

AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds,

AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT); and
- (3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension,

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					Price for Max.	Qty	
					\$	\$	

drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
	Authority required						
	Pulmonary arterial hypertension (PAH)						
	Treatment Phase: Initial 2 (new patients)						
	Clinical criteria:						
	Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,						
	AND						
	Patient must have been assessed by a physician at a designated hospital,						
	AND						
	Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR						
	Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditary PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR						
	Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR						
	Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds,						
	AND						
	The treatment must be the sole PBS-subsidised PAH agent for this condition.						
	Applications for authorisation must be in writing and must include:						
	(1) a completed authority prescription form; and						
	(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:						
	(i) RHC composite assessment; and						
	(ii) ECHO composite assessment; and						
	(iii) 6 Minute Walk Test (6MWT); and						
	(3) a signed patient acknowledgement.						
	Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:						
	(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or						
	(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.						
	Test requirements to establish baseline for initiation of treatment are as follows:						
	The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.						
	Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:						
	(1) RHC plus ECHO composite assessments;						
	(2) RHC composite assessment plus 6MWT;						
	(3) RHC composite assessment only.						
	In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:						
	(1) ECHO composite assessment plus 6MWT;						
	(2) ECHO composite assessment only.						
	Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.						
	The test results provided must not be more than 2 months old at the time of application.						
	The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.						
	A maximum of 5 repeats may be requested.						
	The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.						
	Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.						

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					Price for Max.	Qty	
					\$	\$	

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

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Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
- (3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					\$	\$	

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note

Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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Applications for authority to prescribe should be forwarded to:

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Note

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Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition,

AND

The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

Note

Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (all patients)

Clinical criteria:

Patient must have received approval for initial PBS-subsidised treatment with this agent,

AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent,

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					Price for Max.	Qty	
					\$	\$	

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
 - (i) RHC composite assessment; and
 - (ii) ECHO composite assessment; and
 - (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

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					Qty \$	
Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.						
1308W	tadalafil 20 mg tablet, 56	1	..	..	838.53	Adcirca
						LY

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					Price for Max. Qty \$	

SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

HYPOTHALAMIC HORMONES

Somatostatin and analogues

LANREOTIDE

Authority required (STREAMLINED)

4570

Acromegaly

Clinical criteria:

The condition must be active,

AND

Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre,

AND

The treatment must be after failure of other therapy including dopamine agonists; OR

The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR

The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated,

AND

The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose),

AND

The treatment must cease if IGF1 is not lower after 3 months of treatment.

In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

Authority required (STREAMLINED)

4575

Functional carcinoid tumour

Clinical criteria:

The condition must be causing intractable symptoms,

AND

Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents,

AND

Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate,

AND

The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

5779E	lanreotide 120 mg injection, 1 syringe	2	5	..	*4480.00	Somatuline Autogel	IS
5777C	lanreotide 60 mg injection, 1 syringe	2	5	..	*2690.00	Somatuline Autogel	IS
5778D	lanreotide 90 mg injection, 1 syringe	2	5	..	*3580.00	Somatuline Autogel	IS

LANREOTIDE

Authority required (STREAMLINED)

4567

Acromegaly

Clinical criteria:

The condition must be active,

AND

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer	
					Price for Max. Qty \$		
Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre,							
AND							
The treatment must be after failure of other therapy including dopamine agonists; OR							
The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR							
The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated,							
AND							
The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (6 weeks after the last dose),							
AND							
The treatment must cease if IGF1 is not lower after 3 months of treatment.							
In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.							
5776B	lanreotide 30 mg injection: modified release [1 x 30 mg vial] (&) inert substance diluent [1 x 2 mL ampoule], 1 pack	2	11	..	*1500.00	Somatuline LA	IS
OCTREOTIDE							
<u>Authority required (STREAMLINED)</u>							
4563							
Acromegaly							
Clinical criteria:							
The condition must be controlled with octreotide immediate release injections,							
AND							
The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose),							
AND							
The treatment must cease if IGF1 is not lower after 3 months of treatment.							
In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission							
<u>Authority required (STREAMLINED)</u>							
4561							
Functional carcinoid tumour							
Clinical criteria:							
Patient must have achieved symptom control on octreotide immediate release injections,							
AND							
The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.							
Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.							
<u>Authority required (STREAMLINED)</u>							
4564							
Vasoactive intestinal peptide secreting tumour (VIPoma)							
Clinical criteria:							
Patient must have achieved symptom control on octreotide immediate release injections,							
AND							
The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.							
Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.							
9511N	octreotide 10 mg injection: modified release [1 x 10 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack	2	5	..	*2613.72	Sandostatin LAR	NV
9512P	octreotide 20 mg injection: modified release [1 x 20 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack	2	5	..	*3479.62	Sandostatin LAR	NV
9513Q	octreotide 30 mg injection: modified release [1 x 30 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack	2	5	..	*4354.92	Sandostatin LAR	NV

OCTREOTIDE

Authority required (STREAMLINED)

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer	
					Qty \$			
3407								
Active acromegaly in a patient with persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre AND								
(a) after failure of other therapy including dopamine agonists; or								
(b) as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or								
(c) if the patient is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated.								
In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks. Octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.								
Treatment must cease if IGF1 is not lower after 3 months treatment at a dose of 100 micrograms 3 times daily								
<u>Authority required (STREAMLINED)</u>								
3408								
Functional carcinoid tumour or vasoactive intestinal peptide secreting tumour (VIPoma) causing intractable symptoms. The patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, and surgery or antineoplastic therapy must have failed or be inappropriate.								
Treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose								
9509L	octreotide 100 microgram/mL injection, 5 x 1 mL ampoules	18	11	..	*1236.42	a	Hospira Pty Limited	HH
						a	Octreotide (SUN)	ZF
						a	Octreotide MaxRx	GQ
						a	Sandostatin 0.1	NV
9508K	octreotide 50 microgram/mL injection, 5 x 1 mL ampoules	18	11	..	*619.02	a	Hospira Pty Limited	HH
						a	Octreotide (SUN)	ZF
						a	Octreotide MaxRx	GQ
						a	Sandostatin 0.05	NV
9510M	octreotide 500 microgram/mL injection, 5 x 1 mL ampoules	18	11	..	*6194.52	a	Hospira Pty Limited	HH
						a	Octreotide (SUN)	ZF
						a	Octreotide MaxRx	GQ
						a	Sandostatin 0.5	NV

CALCIUM HOMEOSTASIS

ANTI-PARATHYROID AGENTS

Other anti-parathyroid agents

CINACALCET

Authority required (STREAMLINED)

3323

Management, including initiation and stabilisation, by a nephrologist, of a patient with chronic kidney disease on dialysis who has sustained secondary hyperparathyroidism with iPTH of at least 50 pmol per L, not responding to conventional therapy

Authority required (STREAMLINED)

3324

Management, including initiation and stabilisation, by a nephrologist, of a patient with chronic kidney disease on dialysis who has sustained secondary hyperparathyroidism with iPTH of at least 15 pmol per L and less than 50 pmol per L AND an (adjusted) serum calcium concentration at least 2.6 mmol per L, not responding to conventional treatment

Note

During the titration phase, intact PTH should be monitored 4 weekly (measured at least 12 hours post dose) and dose titrated until an appropriate iPTH concentration is achieved. During the titration phase, approval will be limited to sufficient supply for 4 weeks treatment at a time, with doses between 30 and 180 mg per day according to the patient's response and tolerability.

During the maintenance phase, approval will be limited to provide sufficient quantity for 4 weeks treatment up to a maximum of 6 months supply for doses between 30 and 180 mg per day according to the patient's response and tolerability. Intact PTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.

"Sustained" means the abnormality was detected on at least 2 blood samples collected over a period of 2 to 4 months.

Note

Special Pricing Arrangements apply.

5621W	cinacalcet 30 mg tablet, 28	2	5	..	*385.92		Sensipar	AN
5622X	cinacalcet 60 mg tablet, 28	2	5	..	*771.84		Sensipar	AN
5623Y	cinacalcet 90 mg tablet, 28	2	5	..	*1157.76		Sensipar	AN

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Dispensed Price for Max.						
Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Qty \$	Brand Name and Manufacturer

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

ANTIINFECTIVES FOR SYSTEMIC USE

ANTIBACTERIALS FOR SYSTEMIC USE

MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

Macrolides

AZITHROMYCIN

Authority required (STREAMLINED)

3317

Prophylaxis against Mycobacterium avium complex infections in HIV-positive patients with CD4 cell counts of less than 75 per cubic millimetre

5616N	azithromycin 600 mg tablet, 8	2	5	..	*128.06	Zithromax	PF

CLARITHROMYCIN

Authority required (STREAMLINED)

3325

Treatment of Mycobacterium avium complex infections

5625C	clarithromycin 250 mg tablet, 100	1	2	..	20.00	Klacid	GO

5624B	clarithromycin 500 mg tablet, 100	1	2	..	39.93	Klacid	GO

ANTIMYCOBACTERIALS

DRUGS FOR TREATMENT OF TUBERCULOSIS

Antibiotics

RIFABUTIN

Authority required (STREAMLINED)

3415

Treatment of Mycobacterium avium complex infections in HIV-positive patients

Authority required (STREAMLINED)

3317

Prophylaxis against Mycobacterium avium complex infections in HIV-positive patients with CD4 cell counts of less than 75 per cubic millimetre

9541E	rifabutin 150 mg capsule, 30	4	5	..	*647.36	Mycobutin	PF

ANTIVIRALS FOR SYSTEMIC USE

DIRECT ACTING ANTIVIRALS

Nucleosides and nucleotides excl. reverse transcriptase inhibitors

GANCICLOVIR

Authority required (STREAMLINED)

3379

Cytomegalovirus retinitis in severely immunocompromised patients

Authority required (STREAMLINED)

3380

Prophylaxis of cytomegalovirus disease in bone marrow transplant patients at risk of cytomegalovirus disease

Authority required (STREAMLINED)

3381

Prophylaxis of cytomegalovirus disease in solid organ transplant patients at risk of cytomegalovirus disease

5749N	ganciclovir 500 mg injection, 5 x 500 mg vials	2	1	..	*560.00	Cymevene	RO

VALACICLOVIR

Authority required (STREAMLINED)

3419

Prophylaxis of cytomegalovirus (CMV) infection and disease following renal transplantation in patients at risk of CMV disease

9568N	valaciclovir 500 mg tablet, 100	5	2	..	*606.00	^a APO-Valaciclovir	TX

						^a Valaciclovir RBX	RA

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty	Brand Name and Manufacturer	
					\$		
						a	AS
						a	UA

VALGANCICLOVIR

Authority required (STREAMLINED)

3420

Cytomegalovirus retinitis in patients with acquired immunodeficiency syndrome

Authority required (STREAMLINED)

3421

Prophylaxis of cytomegalovirus infection and disease in solid organ transplant patients at risk of cytomegalovirus disease

9569P	valganciclovir 450 mg tablet, 60	2	5	..	*4491.60	Valcyte	RO

9655E	valganciclovir 50 mg/mL oral liquid: powder for, 100 mL	11	5	..	*4574.79	Valcyte	RO

Phosphonic acid derivatives

FOSCARNET

Authority required (STREAMLINED)

3322

Treatment of cytomegalovirus retinitis in patients with AIDS

Authority required (STREAMLINED)

3378

Treatment of aciclovir-resistant herpes simplex virus infection in immunocompromised patients with HIV infection

5747L	FOSCARNET SODIUM I.V. infusion 24 mg per mL, 250 mL bottle, 6	1	1	..	1177.50	Foscavir	IX

Protease inhibitors

ATAZANAVIR

Authority required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naive,

AND

The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received PBS-subsidised therapy for HIV infection,

AND

The treatment must be in combination with other antiretroviral agents.

5613K	atazanavir 150 mg capsule, 60	2	5	..	*1043.82	Reyataz	BQ

5614L	atazanavir 200 mg capsule, 60	2	5	..	*1391.76	Reyataz	BQ

5612J	atazanavir 300 mg capsule, 30	2	5	..	*1043.82	Reyataz	BQ

BOCEPREVIR

Authority required (STREAMLINED)

4182

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease,

AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	AND					
	The treatment must be in combination with peginterferon alfa and ribavirin,					
	AND					
	The treatment must be limited to a maximum duration of 32 weeks in patients without hepatic cirrhosis who were partial responders or relapsers to the prior course of interferon based therapy for hepatitis C; OR					
	The treatment must be limited to a maximum duration of 44 weeks in patients without hepatic cirrhosis who were null responders to the prior course of interferon based therapy for hepatitis C; OR					
	The treatment must be limited to a maximum duration of 44 weeks for all patients with hepatic cirrhosis,					
	AND					
	The treatment must cease after the first 8 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 12,					
	AND					
	The treatment must cease after the first 20 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 24.					
	Population criteria:					
	Patient must be 18 years or older,					
	AND					
	Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.					
	Treatment criteria:					
	Must be treated in an accredited treatment centre.					
	Chronic genotype 1 hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.					
	Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised boceprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal.					
	Details of the intolerance must be documented in the patient's medical records.					
	For patients without hepatic cirrhosis who were partial responders or relapsers to the prior course of interferon based therapy, a maximum of 7 repeats may be prescribed.					
	For patients without hepatic cirrhosis who were null responders to the prior course of interferon based therapy, a maximum of 10 repeats may be prescribed.					
	For patients with hepatic cirrhosis, a maximum of 10 repeats may be prescribed.					
	<u>Authority required (STREAMLINED)</u>					
	4202					
	Chronic genotype 1 hepatitis C infection					
	Clinical criteria:					
	Patient must have compensated liver disease,					
	AND					
	Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,					
	AND					
	The treatment must be in combination with peginterferon alfa and ribavirin,					
	AND					
	The treatment must be limited to a maximum duration of 24 weeks in patients without hepatic cirrhosis; OR					
	The treatment must be limited to a maximum duration of 44 weeks in patients with hepatic cirrhosis,					
	AND					
	The treatment must cease after the first 20 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 24.					
	Population criteria:					
	Patient must be 18 years or older,					
	AND					
	Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.					
	Treatment criteria:					
	Must be treated in an accredited treatment centre.					
	Evidence of chronic genotype 1 hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.					
	Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised boceprevir, except where					

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.	Brand Name and Manufacturer	
					Qty \$		
	the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records.						
	For patients without hepatic cirrhosis, a maximum of 5 repeats may be prescribed.						
	For patients with hepatic cirrhosis, a maximum of 10 repeats may be prescribed.						
	<u>Note</u>						
	No increase in the maximum quantity or number of units may be authorised.						
	<u>Note</u>						
	Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:						
	(a) a nurse educator/counsellor for patients; and						
	(b) 24-hour access by patients to medical advice; and						
	(c) an established liver clinic.						
2433C	Boceprevir 200 mg capsule, 336 capsules	1	10	..	3920.00	Victrelis	MK

DARUNAVIR

Authority required (STREAMLINED)

3595

Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents, and co-administered with 100 mg ritonavir twice daily in an antiretroviral experienced patient who, after at least one antiretroviral regimen, has experienced virological failure or clinical failure or genotypic resistance.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity

5653M	darunavir 150 mg tablet, 240	1	5	..	1048.71	Prezista	JC
3392M	darunavir 600 mg tablet, 60	2	5	..	*2097.42	Prezista	JC

DARUNAVIR

Authority required (STREAMLINED)

4313

Human immunodeficiency virus (HIV) infection

Clinical criteria:

The treatment must be in addition to optimised background therapy,

AND

The treatment must be in combination with other antiretroviral agents,

AND

The treatment must be co-administered with 100 mg ritonavir,

AND

Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen,

AND

Patient must not have demonstrated darunavir resistance associated mutations detected on resistance testing.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

2980W	darunavir 800 mg tablet, 30	2	5	..	*1398.28	Prezista	JC

FOSAMPRENAVIR

Authority required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naive,

AND

The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4454

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.	Brand Name and Manufacturer	
					Qty \$		
	HIV infection						
	Treatment Phase: Continuing						
	Clinical criteria:						
	Patient must have previously received PBS-subsidised therapy for HIV infection,						
	AND						
	The treatment must be in combination with other antiretroviral agents.						
5745J	fosamprenavir 50 mg/mL oral liquid, 225 mL	8	5	..	*812.48	Telzir	VI
5746K	fosamprenavir 700 mg tablet, 60	2	5	..	*758.32	Telzir	VI

INDINAVIR

Authority required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naive,

AND

The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received PBS-subsidised therapy for HIV infection,

AND

The treatment must be in combination with other antiretroviral agents.

5752R	indinavir 400 mg capsule, 180	2	5	..	*910.00	Crixivan 400 mg	MK

RITONAVIR

Authority required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naive,

AND

The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received PBS-subsidised therapy for HIV infection,

AND

The treatment must be in combination with other antiretroviral agents.

9660K	ritonavir 100 mg tablet, 30	24	5	..	*982.80	Norvir	VE
9542F	ritonavir 600 mg/7.5 mL oral liquid, 90 mL	10	5	..	*910.00	Norvir	VE

SAQUINAVIR

Authority required (STREAMLINED)

4512

HIV infection

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	
	Treatment Phase: Initial					
	Clinical criteria:					
	Patient must be antiretroviral treatment naive,					
	AND					
	The treatment must be in combination with other antiretroviral agents.					
	<u>Authority required (STREAMLINED)</u>					
	4454					
	HIV infection					
	Treatment Phase: Continuing					
	Clinical criteria:					
	Patient must have previously received PBS-subsidised therapy for HIV infection,					
	AND					
	The treatment must be in combination with other antiretroviral agents.					
9545J	saquinavir 500 mg tablet, 120	2	5	..	*1011.12	Invirase RO

SIMEPREVIR

Authority required (STREAMLINED)

4758

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease,

AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

AND

The treatment must be in combination with peginterferon alfa and ribavirin,

AND

The treatment must be limited to a maximum duration of 12 weeks,

AND

The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is 25 IU/mL or greater.

Population criteria:

Patient must be aged 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised simeprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records.

Authority required (STREAMLINED)

4759

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease,

AND

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

AND

The treatment must be in combination with peginterferon alfa and ribavirin,

AND

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	The treatment must be limited to a maximum duration of 12 weeks, AND The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is 25 IU/mL or greater. Population criteria: Patient must be 18 years or older, AND Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age. Treatment criteria: Must be treated in an accredited treatment centre. Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records. Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised simeprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records. <u>Note</u> No increase in the maximum quantity or number of units may be authorised. <u>Note</u> No increase in the maximum number of repeats may be authorised. <u>Note</u> Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C: (a) a nurse educator/counsellor for patients; and (b) 24-hour access by patients to medical advice; and (c) an established liver clinic.					
10200W	simeprevir sodium 150 mg capsule, 7	6	..	..	*14865.72	Olysio

JC

TELAPREVR

Authority required (STREAMLINED)

4186

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease,

AND

Patient must not have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

AND

The treatment must be in combination with peginterferon alfa and ribavirin,

AND

The treatment must be limited to a maximum duration of 12 weeks,

AND

The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL.

Population criteria:

Patient must be 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised telaprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty	\$	
<u>Authority required (STREAMLINED)</u>							
4191							
Chronic genotype 1 hepatitis C infection							
Clinical criteria:							
Patient must have compensated liver disease,							
AND							
Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C,							
AND							
The treatment must be in combination with peginterferon alfa and ribavirin,							
AND							
The treatment must be limited to a maximum duration of 12 weeks,							
AND							
The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL.							
Population criteria:							
Patient must be 18 years or older,							
AND							
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.							
Treatment criteria:							
Must be treated in an accredited treatment centre.							
Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.							
Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised telaprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records.							
<u>Note</u>							
No increase in the maximum quantity or number of units may be authorised.							
<u>Note</u>							
No increase in the maximum number of repeats may be authorised.							
<u>Note</u>							
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:							
(a) a nurse educator/counsellor for patients; and							
(b) 24-hour access by patients to medical advice; and							
(c) an established liver clinic.							
2437G	telaprevir 375 mg tablet, 42	6	..	..	*14865.72	Incivo	JC
TIPRANAVIR							
<u>Authority required (STREAMLINED)</u>							
3601							
Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents, and co-administered with 200 mg ritonavir twice daily in an antiretroviral experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance.							
Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity							
<u>Note</u>							
Special Pricing Arrangements apply.							
9567M	tipranavir 250 mg capsule, 120	2	5	..	*2142.00	Aptivus	BY

Nucleoside and nucleotide reverse transcriptase inhibitors

ABACAVIR

Authority required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer	
					Price for Max. Qty \$		
Clinical criteria: Patient must be antiretroviral treatment naive, AND The treatment must be in combination with other antiretroviral agents. <u>Authority required (STREAMLINED)</u> 4454 HIV infection Treatment Phase: Continuing							
Clinical criteria: Patient must have previously received PBS-subsidised therapy for HIV infection, AND The treatment must be in combination with other antiretroviral agents.							
5602W	abacavir 20 mg/mL oral liquid, 240 mL	8	5	..	*657.12	Ziagen	VI
5601T	abacavir 300 mg tablet, 60	2	5	..	*564.00	Ziagen	VI
ADEFOVIR DIPIVOXIL <u>Authority required (STREAMLINED)</u> 3973 Chronic hepatitis B in a patient without cirrhosis who has failed antihepadnaviral therapy and who satisfies all of the following criteria: (a) Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or (b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance <u>Authority required (STREAMLINED)</u> 3974 Chronic hepatitis B in a patient with cirrhosis who has failed antihepadnaviral therapy and who has detectable HBV DNA. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy <u>Note</u> Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.							
5606C	adefovir dipivoxil 10 mg tablet, 30	2	5	..	*1050.00	^a APO-Adefovir ^a Hepsera	TX GI
DIDANOSINE <u>Authority required (STREAMLINED)</u> 4512 HIV infection Treatment Phase: Initial							
Clinical criteria: Patient must be antiretroviral treatment naive, AND The treatment must be in combination with other antiretroviral agents. <u>Authority required (STREAMLINED)</u> 4454 HIV infection Treatment Phase: Continuing							
Clinical criteria: Patient must have previously received PBS-subsidised therapy for HIV infection, AND The treatment must be in combination with other antiretroviral agents.							
5663C	didanosine 125 mg capsule: enteric, 30	2	5	..	*280.86	Videx EC	BQ
5664D	didanosine 200 mg capsule: enteric, 30	2	5	..	*326.80	Videx EC	BQ
5665E	didanosine 250 mg capsule: enteric, 30	2	5	..	*408.48	Videx EC	BO

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer	
					Price for Max. Qty \$		
5666F	didanosine 400 mg capsule: enteric, 30	2	5	..	*653.58	Videx EC	BQ

EMTRICITABINE

Authority required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naive,

AND

The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received PBS-subsidised therapy for HIV infection,

AND

The treatment must be in combination with other antiretroviral agents.

5709L	emtricitabine 200 mg capsule, 30	2	5	..	*564.00	Emtriva	GI

ENTECAVIR

Authority required (STREAMLINED)

3964

Chronic hepatitis B in a patient without cirrhosis who has failed lamivudine and who satisfies all of the following criteria:

(a) Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or

(b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance

Authority required (STREAMLINED)

3966

Chronic hepatitis B in a patient with cirrhosis who has failed lamivudine and who has detectable HBV DNA.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy

Note

PBS-subsidised entecavir monohydrate must be used as monotherapy.

5712P	entecavir monohydrate 1 mg tablet, 30	2	5	..	*1250.00	Baraclude	BQ

ENTECAVIR

Authority required (STREAMLINED)

3961

Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria:

(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;

(2) Evidence of chronic liver injury as determined by:

(a) Confirmed elevated serum ALT; or

(b) Liver biopsy

Authority required (STREAMLINED)

3962

Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy

Note

PBS-subsidised entecavir monohydrate must be used as monotherapy.

5711N	entecavir monohydrate 500 microgram tablet, 30	2	5	..	*768.60	Baraclude	BQ

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty \$		
LAMIVUDINE <u>Authority required (STREAMLINED)</u> 4512 HIV infection Treatment Phase: Initial Clinical criteria: Patient must be antiretroviral treatment naive, AND The treatment must be in combination with other antiretroviral agents. <u>Authority required (STREAMLINED)</u> 4454 HIV infection Treatment Phase: Continuing Clinical criteria: Patient must have previously received PBS-subsidised therapy for HIV infection, AND The treatment must be in combination with other antiretroviral agents.							
5773W	lamivudine 10 mg/mL oral liquid, 240 mL	8	5	..	*447.84	3TC	VI
5772T	lamivudine 150 mg tablet, 60	2	5	..	*306.68	^a 3TC	VI
5774X	lamivudine 300 mg tablet, 30	2	5	..	*306.68	^a Lamivudine	AF
						^a Alphapharm	
						^a Lamivudine RBX	RA
						^a 3TC	VI
						^a Lamivudine	AF
						^a Alphapharm	
						^a Lamivudine RBX	RA
LAMIVUDINE <u>Authority required (STREAMLINED)</u> 3961 Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria: (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection; (2) Evidence of chronic liver injury as determined by: (a) Confirmed elevated serum ALT; or (b) Liver biopsy <u>Authority required (STREAMLINED)</u> 3962 Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy							
5770Q	lamivudine 100 mg tablet, 28	2	5	..	*162.44	^a Zeffix	AS
5771R	lamivudine 5 mg/mL oral liquid, 240 mL	5	5	..	*226.25	^a Zetlam	AF
						Zeffix	AS

STAVUDINE

Authority required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naive,

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

[illegible]

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	
	Patient must not have cirrhosis, AND Patient must be nucleoside analogue naive, AND Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, AND Patient must have evidence of chronic liver injury determined by: (i) confirmed elevated serum ALT; or (ii) liver biopsy, AND The treatment must be the sole PBS-subsidised therapy for this condition. Note Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy. Authority required (STREAMLINED) 4476 Chronic hepatitis B Clinical criteria: Patient must have cirrhosis, AND Patient must be nucleoside analogue naive, AND Patient must have detectable HBV DNA, AND The treatment must be the sole PBS-subsidised therapy for this condition. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy. Note Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy. Authority required (STREAMLINED) 4490 Chronic hepatitis B Clinical criteria: Patient must not have cirrhosis, AND Patient must have failed antihepadnaviral therapy, AND Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; OR Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance. Note Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy. Authority required (STREAMLINED) 4510 Chronic hepatitis B Clinical criteria: Patient must have cirrhosis, AND Patient must have failed antihepadnaviral therapy, AND Patient must have detectable HBV DNA. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.	Brand Name and Manufacturer	
					Qty \$		
<u>Note</u>							
Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.							
9563H	tenofovir disoproxil fumarate 300 mg tablet, 30	2	5	..	*966.20	Viread	GI
ZIDOVUDINE							
<u>Authority required (STREAMLINED)</u>							
4512							
HIV infection							
Treatment Phase: Initial							
Clinical criteria:							
Patient must be antiretroviral treatment naive,							
AND							
The treatment must be in combination with other antiretroviral agents.							
<u>Authority required (STREAMLINED)</u>							
4454							
HIV infection							
Treatment Phase: Continuing							
Clinical criteria:							
Patient must have previously received PBS-subsidised therapy for HIV infection,							
AND							
The treatment must be in combination with other antiretroviral agents.							
9651Y	zidovudine 100 mg capsule, 100	4	5	..	*821.84	Retrovir	VI
9652B	zidovudine 250 mg capsule, 40	6	5	..	*1232.76	Retrovir	VI
9570Q	zidovudine 50 mg/5 mL oral liquid, 200 mL	15	5	..	*673.20	Retrovir	VI

Non-nucleoside reverse transcriptase inhibitors

EFAVIRENZ

Authority required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naive,

AND

The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received PBS-subsidised therapy for HIV infection,

AND

The treatment must be in combination with other antiretroviral agents.

5708K	efavirenz 200 mg tablet, 90	2	5	..	*543.16	Stocrin	MK
5707J	efavirenz 30 mg/mL oral liquid, 180 mL	7	5	..	*570.29	Stocrin	MK
5706H	efavirenz 600 mg tablet, 30	2	5	..	*543.16	Stocrin	MK

ETRAVIRINE

Authority required (STREAMLINED)

3597

Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents in an antiretroviral

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer	
					Price for Max. Qty \$		
experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance.							
Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity							
5084N	etravirine 200 mg tablet, 60	2	5	..	*1233.00	Intelence	JC

NEVIRAPINE

Authority required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naive,

AND

The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received PBS-subsidised therapy for HIV infection,

AND

The treatment must be in combination with other antiretroviral agents.

9507J	nevirapine 10 mg/mL oral liquid, 240 mL	10	5	..	*1350.00	Viramune	BY
9506H	nevirapine 200 mg tablet, 60	2	5	..	*396.18	^a Nevipin	GN
						^a Nevirapine Alphapharm	AF
						^a Nevirapine RBX	RA
						^a Viramune	BY

NEVIRAPINE

Authority required (STREAMLINED)

4526

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must have been stabilised on nevirapine immediate release,

AND

The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received PBS-subsidised therapy for HIV infection,

AND

The treatment must be in combination with other antiretroviral agents.

1132N	nevirapine 400 mg tablet: modified release, 30 tablets	2	5	..	*396.18	Viramune XR	BY

RILPIVIRINE

Authority required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	
	Patient must be antiretroviral treatment naive, AND The treatment must be in combination with other antiretroviral agents. <u>Authority required (STREAMLINED)</u> 4454 HIV infection Treatment Phase: Continuing Clinical criteria: Patient must have previously received PBS-subsidised therapy for HIV infection, AND The treatment must be in combination with other antiretroviral agents.					
1173R	rilpivirine 25 mg tablet, 30	2	5	..	*543.16	Edurant
						JC

Antivirals for treatment of HIV infections, combinations

ABACAVIR + LAMIVUDINE

Authority required (STREAMLINED)

4527

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naive,

AND

The treatment must be in combination with other antiretroviral agents.

Population criteria:

Patient must be aged 12 years or older,

AND

Patient must weigh 40 kg or more.

Authority required (STREAMLINED)

4528

HIV infection

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received PBS-subsidised therapy for HIV infection,

AND

The treatment must be in combination with other antiretroviral agents.

Population criteria:

Patient must be aged 12 years or older,

AND

Patient must weigh 40 kg or more.

5603X	abacavir 600 mg + lamivudine 300 mg tablet, 30	2	5	..	*870.68	Kivexa	VI

ABACAVIR + LAMIVUDINE + ZIDOVUDINE

Authority required (STREAMLINED)

4495

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naive.

Population criteria:

Patient must be aged 12 years or older,

AND

Patient must weigh 40 kg or more.

Authority required (STREAMLINED)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer	
	4480 HIV infection Treatment Phase: Continuing Clinical criteria: Patient must have previously received PBS-subsidised therapy for HIV infection. Population criteria: Patient must be aged 12 years or older, AND Patient must weigh 40 kg or more.						
5604Y	abacavir 300 mg + lamivudine 150 mg + zidovudine 300 mg tablet, 60	2	5	..	*1357.28	Trizivir	VI
	DOLUTEGRAVIR + ABACAVIR + LAMIVUDINE <u>Authority required (STREAMLINED)</u> 4495 HIV infection Treatment Phase: Initial Clinical criteria: Patient must be antiretroviral treatment naive. Population criteria: Patient must be aged 12 years or older, AND Patient must weigh 40 kg or more. <u>Authority required (STREAMLINED)</u>						
	4480 HIV infection Treatment Phase: Continuing Clinical criteria: Patient must have previously received PBS-subsidised therapy for HIV infection. Population criteria: Patient must be aged 12 years or older, AND Patient must weigh 40 kg or more.						
10247H	dolutegravir 50 mg + abacavir 600 mg + lamivudine 300 mg tablet, 30	2	5	..	*2073.36	Triumeq	VI
	EMTRICITABINE + RILPIVIRINE + TENOFOVIR <u>Authority required (STREAMLINED)</u> 4522 HIV infection Treatment Phase: Initial Clinical criteria: Patient must be antiretroviral treatment naive. <u>Authority required (STREAMLINED)</u>						
	4470 HIV infection Treatment Phase: Continuing Clinical criteria: Patient must have previously received PBS-subsidised therapy for HIV infection.						
1491L	emtricitabine 200 mg + rilpivirine 25 mg + tenofovir disoproxil fumarate 300 mg tablet, 30	2	5	..	*2073.36	Eviplera	GI
	LAMIVUDINE + ZIDOVUDINE <u>Authority required (STREAMLINED)</u> 4512 HIV infection						

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer	
	Treatment Phase: Initial Clinical criteria: Patient must be antiretroviral treatment naive, AND The treatment must be in combination with other antiretroviral agents. <u>Authority required (STREAMLINED)</u> 4454 HIV infection Treatment Phase: Continuing Clinical criteria: Patient must have previously received PBS-subsidised therapy for HIV infection, AND The treatment must be in combination with other antiretroviral agents.						
5775Y	lamivudine 150 mg + zidovudine 300 mg tablet, 60	2	5	..	*787.46	^a Combivir	VI
						^a Lamivudine 150 mg + Zidovudine 300 mg Alphapharm	AF
	LOPINAVIR + RITONAVIR <u>Authority required (STREAMLINED)</u> 4512 HIV infection Treatment Phase: Initial Clinical criteria: Patient must be antiretroviral treatment naive, AND The treatment must be in combination with other antiretroviral agents. <u>Authority required (STREAMLINED)</u> 4454 HIV infection Treatment Phase: Continuing Clinical criteria: Patient must have previously received PBS-subsidised therapy for HIV infection, AND The treatment must be in combination with other antiretroviral agents.						
5790R	lopinavir 100 mg + ritonavir 25 mg tablet, 60	2	5	..	*342.50	Kaletra	VE
5791T	lopinavir 200 mg + ritonavir 50 mg tablet, 120	2	5	..	*1370.00	Kaletra	VE
5789Q	lopinavir 400 mg/5 mL + ritonavir 100 mg/5 mL oral liquid, 60 mL	10	5	..	*1290.00	Kaletra	VE
	TENOFOVIR + EMTRICITABINE <u>Authority required (STREAMLINED)</u> 4512 HIV infection Treatment Phase: Initial Clinical criteria: Patient must be antiretroviral treatment naive, AND The treatment must be in combination with other antiretroviral agents. <u>Authority required (STREAMLINED)</u> 4454 HIV infection Treatment Phase: Continuing Clinical criteria:						

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer	
					Price for Max. Qty \$		
	Patient must have previously received PBS-subsidised therapy for HIV infection, AND The treatment must be in combination with other antiretroviral agents.						
9564J	tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg tablet, 30	2	5	..	*1530.20	Truvada	GI
	TENOFOVIR + EMTRICITABINE + EFAVIRENZ <u>Authority required (STREAMLINED)</u> 4522 HIV infection Treatment Phase: Initial Clinical criteria: Patient must be antiretroviral treatment naive. <u>Authority required (STREAMLINED)</u> 4470 HIV infection Treatment Phase: Continuing Clinical criteria: Patient must have previously received PBS-subsidised therapy for HIV infection.						
9565K	tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg + efavirenz 600 mg tablet, 30	2	5	..	*2073.36	Atripla	GI
	TENOFOVIR + EMTRICITABINE + ELVITEGRAVIR + COBICISTAT <u>Authority required (STREAMLINED)</u> 4522 HIV infection Treatment Phase: Initial Clinical criteria: Patient must be antiretroviral treatment naive. <u>Authority required (STREAMLINED)</u> 4470 HIV infection Treatment Phase: Continuing Clinical criteria: Patient must have previously received PBS-subsidised therapy for HIV infection.						
10088Y	tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg + elvitegravir 150 mg + cobicistat 150 mg tablet, 30	2	5	..	*2073.36	Stribild	GI

Other antivirals

DOLUTEGRAVIR

Authority required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naive,

AND

The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received PBS-subsidised therapy for HIV infection,

AND

The treatment must be in combination with other antiretroviral agents.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer	
					Price for Max. Qty \$		
10065R	dolutegravir 50 mg tablet, 30	2	5	..	*1331.10	Tivicay	VI

ENFUVIRTIDE

Authority required (STREAMLINED)

3597

Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents in an antiretroviral experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity

5710M	enfuvirtide 90 mg injection [60 x 90 mg vials] (&) inert substance diluent [60 x 1.1 mL vials], 1 pack	2	5	..	*4426.00	Fuzeon	RO

MARAVIROC

Authority required (STREAMLINED)

3599

Treatment, in addition to optimised background therapy in combination with other antiretroviral agents, of an antiretroviral experienced patient infected with only CCR5-tropic HIV-1, who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance. A tropism assay to determine CCR5 only strain status is required prior to initiation. Individuals with CXCR4 tropism demonstrated at any time point are not eligible.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity

5792W	maraviroc 150 mg tablet, 60	2	5	..	*1835.40	Celsentri	VI
5793X	maraviroc 300 mg tablet, 60	2	5	..	*1835.40	Celsentri	VI

RALTEGRAVIR

Authority required (STREAMLINED)

4275

HIV infection

Treatment Phase: Initial

Clinical criteria:

The treatment must be in combination with other antiretroviral agents,

AND

Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy,

AND

Patient must have a CD4 count of less than 500 per cubic millimetre; OR

Patient must have symptomatic HIV disease.

Population criteria:

Patient must be aged 2 years or older.

Authority required (STREAMLINED)

4274

HIV infection

Treatment Phase: Continuing

Clinical criteria:

The treatment must be in combination with other antiretroviral agents,

AND

Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy,

AND

Patient must have previously received PBS-subsidised therapy for HIV infection.

Population criteria:

Patient must be aged 2 years or older.

2760G	raltegravir 100 mg tablet: chewable, 60	6	5	..	*2025.00	Isentress	MK
2736B	raltegravir 25 mg tablet: chewable, 60	6	5	..	*506.28	Isentress	MK

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer	
RALTEGRAVIR							
<u>Authority required (STREAMLINED)</u>							
4512							
HIV infection							
Treatment Phase: Initial							
Clinical criteria:							
Patient must be antiretroviral treatment naive,							
AND							
The treatment must be in combination with other antiretroviral agents.							
<u>Authority required (STREAMLINED)</u>							
4454							
HIV infection							
Treatment Phase: Continuing							
Clinical criteria:							
Patient must have previously received PBS-subsidised therapy for HIV infection,							
AND							
The treatment must be in combination with other antiretroviral agents.							
9523F	raltegravir 400 mg tablet, 60	2	5	..	*1331.10	Isentress	MK

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

ANTINEOPLASTIC AGENTS

ANTIMETABOLITES

Pyrimidine analogues

AZACITIDINE

Authority required

Initial PBS-subsidised treatment of a patient with:

- (1) Myelodysplastic syndrome classified as Intermediate-2 or high risk according to the International Prognostic Scoring System (IPSS); OR
- (2) Chronic Myelomonocytic Leukaemia (10% to 29% marrow blasts without Myeloproliferative Disorder); OR
- (3) Acute Myeloid Leukaemia with 20 to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification.

Classification of a patient as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations:

1. 11% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 0 to 1 cytopenias; OR
2. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR
3. 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
4. 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
5. 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; OR
6. less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias.

Classification of a patient as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations:

1. 21% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
2. 21% to 30% marrow blasts with intermediate (other abnormalities) or poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
3. 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
4. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias.

The first authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and
- (c) a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome, chronic myelomonocytic leukaemia or acute myeloid leukaemia; and
- (d) a copy of the full blood examination report; and
- (e) for myelodysplastic syndrome, a copy of the pathology report detailing the cytogenetics demonstrating intermediate-2 or high risk disease according to the International Prognostic Scoring System (IPSS); and
- (f) a signed patient acknowledgment form.

No more than three cycles will be authorised

Note

Any queries concerning the arrangements to prescribe azacitidine may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe azacitidine should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

Special Pricing Arrangements apply.

9597D	azacitidine 100 mg injection, 1 x 100 mg vial	14	2	..	*7700.00	Vidaza	CJ

AZACITIDINE

Authority required

Continuing treatment of a patient with:

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty \$		
	(1) Myelodysplastic syndrome classified as Intermediate-2 or high risk according to the International Prognostic Scoring System (IPSS); OR (2) Chronic Myelomonocytic Leukaemia (10% to 29% marrow blasts without Myeloproliferative Disorder); OR (3) Acute Myeloid Leukaemia with 20 to 30% blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification; who has previously been issued with an authority prescription for azacitidine and does not have progressive disease. Authority applications for continuing treatment may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Up to six cycles will be authorised						
	<u>Note</u> Any queries concerning the arrangements to prescribe azacitidine may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au . Written applications for authority to prescribe azacitidine should be forwarded to: Medicare Australia Prior Written Approval of Specialised Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001						
	<u>Note</u> Special Pricing Arrangements apply.						
9598E	azacitidine 100 mg injection, 1 x 100 mg vial	14	5	..	*7700.00		Vidaza

CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

Anthracyclines and related substances

DOXORUBICIN HYDROCHLORIDE-PEGYLATED LIPOSOMAL

Authority required (STREAMLINED)

3348

Treatment of AIDS-related Kaposi's sarcoma in patients with CD4 cell counts of less than 200 per cubic millimetre and extensive mucocutaneous involvement

Authority required (STREAMLINED)

3349

Treatment of AIDS-related Kaposi's sarcoma in patients with CD4 cell counts of less than 200 per cubic millimetre and extensive visceral involvement

5705G	doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial	4	5	..	*2093.24	^a	Caelyx	JC
						^a	Liposomal Doxorubicin SUN	ZF

OTHER ANTINEOPLASTIC AGENTS

Monoclonal antibodies

ALEMTUZUMAB

Authority required (STREAMLINED)

4834

Multiple sclerosis

Treatment Phase: Initial

Clinical criteria:

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient,

AND

The treatment must be as monotherapy,

AND

Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years,

AND

Patient must be ambulatory (without assistance or support).

Treatment criteria:

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer	
					Price for Max. Qty \$		
	Must be treated by a neurologist.						
	Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application.						
	Note Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.						
	Note Special Pricing Arrangements apply.						
	Note No increase in the maximum quantity or number of units may be authorised.						
	Note No increase in the maximum number of repeats may be authorised.						
10228H	alemtuzumab 12 mg/1.2 mL injection, 1 x 1.2 mL vial	5	..	..	*56970.00	Lemtrada	GZ

ALEMTUZUMAB

Authority required (STREAMLINED)

4829

Multiple sclerosis

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug,

AND

Patient must not show continuing progression of disability while on treatment with this drug,

AND

Patient must not receive more than one PBS-subsidised treatment per year,

AND

The treatment must be as monotherapy,

AND

Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

Treatment criteria:

Must be treated by a neurologist.

Note

Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.

Note

Special Pricing Arrangements apply.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

10232M	alemtuzumab 12 mg/1.2 mL injection, 1 x 1.2 mL vial	3	..	..	*34182.00	Lemtrada	GZ

IMMUNOSTIMULANTS

IMMUNOSTIMULANTS

Colony stimulating factors

FILGRASTIM

Authority required (STREAMLINED)

3357

For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia

Authority required (STREAMLINED)

3358

Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy

Authority required (STREAMLINED)

3359

Mobilisation of peripheral blood progenitor cells, in a normal volunteer, for use in allogeneic transplantation

Authority required (STREAMLINED)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
3360	A patient receiving marrow-ablative chemotherapy and subsequent bone marrow transplantation					
	<u>Authority required (STREAMLINED)</u>					
3361	A patient with a non-myeloid malignancy receiving marrow-ablative chemotherapy and subsequent autologous peripheral blood progenitor cell transplantation					
	<u>Authority required (STREAMLINED)</u>					
3368	A patient with chronic cyclic neutropenia (absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months))					
	<u>Authority required (STREAMLINED)</u>					
3369	A patient with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned					
	<u>Authority required (STREAMLINED)</u>					
3362	A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned					
	<u>Authority required (STREAMLINED)</u>					
3363	A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned					
	<u>Authority required (STREAMLINED)</u>					
3364	A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned					
	<u>Authority required (STREAMLINED)</u>					
3365	A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned					
	<u>Authority required (STREAMLINED)</u>					
3366	A patient with severe congenital neutropenia (absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, and in whom a bone marrow examination has shown evidence of maturational arrest of the neutrophil lineage)					
	<u>Authority required (STREAMLINED)</u>					
3367	A patient with severe chronic neutropenia (absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, or evidence of neutrophil dysfunction, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months))					
	<u>Authority required (STREAMLINED)</u>					
3370	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia					
	<u>Authority required (STREAMLINED)</u>					
3371	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide)					
	<u>Authority required (STREAMLINED)</u>					
3372	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours					
	<u>Authority required (STREAMLINED)</u>					
3373						

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer	
					Price for Max. Qty \$		
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours						
	<u>Authority required (STREAMLINED)</u>						
	3374						
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma						
	<u>Authority required (STREAMLINED)</u>						
	3375						
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen)						
	<u>Authority required (STREAMLINED)</u>						
	3376						
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease						
	<u>Authority required (STREAMLINED)</u>						
	3377						
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma						
	<u>Authority required (STREAMLINED)</u>						
	3834						
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Hodgkin disease (first-line chemotherapy with escalated BEACOPP)						
5829T	filgrastim 120 microgram/0.2 mL injection, 10 x 0.2 mL syringes	2	11	..	*853.28	Nivestim	HH
1123D	filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes	2	11	..	*2133.18	TevaGrastim	AS
5742F	filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes	2	11	..	*2133.18	Neupogen	AN
9692D	filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes	2	11	..	*2133.18	Nivestim	HH
2758E	filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes	4	11	..	*2133.16	Zarzio	SZ
5741E	filgrastim 300 microgram/mL injection, 10 x 1 mL vials	2	11	..	*2133.18	Neupogen	AN
5744H	filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes	2	11	..	*3419.62	Neupogen	AN
9694F	filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes	2	11	..	*3419.62	Nivestim	HH
2783L	filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes	4	11	..	*3419.60	Zarzio	SZ
1126G	filgrastim 480 microgram/0.8 mL injection, 10 x 0.8 mL syringes	2	11	..	*3419.62	TevaGrastim	AS
5743G	filgrastim 480 microgram/1.6 mL injection, 10 x 1.6 mL vials	2	11	..	*3419.62	Neupogen	AN

LENOGRASTIM

Authority required (STREAMLINED)

3395

Patients with breast cancer receiving standard dose adjuvant chemotherapy who have had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required (STREAMLINED)

3396

Patients receiving first-line chemotherapy for Hodgkin's disease who have had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required (STREAMLINED)

3392

Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for reinfusion into patients with non-myeloid malignancies who have had myeloablative or myelosuppressive therapy

Authority required (STREAMLINED)

3393

Mobilisation of peripheral blood progenitor cells, in normal volunteers, for use in allogeneic transplantation to facilitate harvest of such cells in healthy donors

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer	
	<u>Authority required (STREAMLINED)</u>						
	3394						
	Patients with non-myeloid malignancies receiving marrow-ablative chemotherapy and subsequent peripheral blood progenitor cell or bone marrow transplantation						
	<u>Authority required (STREAMLINED)</u>						
	3397						
	Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia						
	<u>Authority required (STREAMLINED)</u>						
	3398						
	Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Ewing's sarcoma						
	<u>Authority required (STREAMLINED)</u>						
	3399						
	Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours						
	<u>Authority required (STREAMLINED)</u>						
	3400						
	Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours						
	<u>Authority required (STREAMLINED)</u>						
	3401						
	Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma						
	<u>Authority required (STREAMLINED)</u>						
	3402						
	Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin's lymphoma (intermediate or high grade)						
	<u>Authority required (STREAMLINED)</u>						
	3403						
	Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in osteosarcoma						
	<u>Authority required (STREAMLINED)</u>						
	3404						
	Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin's disease						
	<u>Authority required (STREAMLINED)</u>						
	3405						
	Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in rhabdomyosarcoma						
5787N	LENOGRASTIM Powder for injection 13,400,000 i.u. (105 micrograms) vial, 10	2	11	..	*1025.00	Granocyte 13	HH
5788P	LENOGRASTIM Powder for injection 33,600,000 i.u. (263 micrograms) vial, 10	2	11	..	*2567.20	Granocyte 34	HH
	PEGFILGRASTIM						
	<u>Authority required (STREAMLINED)</u>						
	3357						
	For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia						
	<u>Authority required (STREAMLINED)</u>						
	3362						
	A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned						
	<u>Authority required (STREAMLINED)</u>						
	3363						
	A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned						
	<u>Authority required (STREAMLINED)</u>						
	3364						
	A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned						
	<u>Authority required (STREAMLINED)</u>						
	3365						

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	
	A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned					
	<u>Authority required (STREAMLINED)</u>					
	3369					
	A patient with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned					
	<u>Authority required (STREAMLINED)</u>					
	3370					
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia					
	<u>Authority required (STREAMLINED)</u>					
	3371					
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide)					
	<u>Authority required (STREAMLINED)</u>					
	3372					
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours					
	<u>Authority required (STREAMLINED)</u>					
	3373					
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours					
	<u>Authority required (STREAMLINED)</u>					
	3374					
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma					
	<u>Authority required (STREAMLINED)</u>					
	3375					
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen)					
	<u>Authority required (STREAMLINED)</u>					
	3376					
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease					
	<u>Authority required (STREAMLINED)</u>					
	3377					
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma					
	<u>Authority required (STREAMLINED)</u>					
	3834					
	A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Hodgkin disease (first-line chemotherapy with escalated BEACOPP)					
9514R	pegfilgrastim 6 mg/0.6 mL injection, 1 x 0.6 mL syringe	1	11	..	1925.00	Neulasta AN

Interferons

INTERFERON ALFA-2A

Authority required (STREAMLINED)

3382

Use in the treatment of Philadelphia chromosome positive myelogenous leukaemia in the chronic phase

Authority required (STREAMLINED)

3961

Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria:

(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;

(2) Evidence of chronic liver injury as determined by:

(a) Confirmed elevated serum ALT; or

(b) Liver biopsy

Authority required (STREAMLINED)

3962

Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer	
					Price for Max. Qty \$		

micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy

Caution

Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

5759D	interferon alfa-2a 3 million international units/0.5 mL injection, 1 x 0.5 mL syringe	30	5	..	*894.00	Roferon-A	RO
5760E	interferon alfa-2a 4.5 million international units/0.5 mL injection, 1 x 0.5 mL syringe	30	5	..	*1341.00	Roferon-A	RO
5761F	interferon alfa-2a 6 million international units/0.5 mL injection, 1 x 0.5 mL syringe	30	5	..	*1787.40	Roferon-A	RO
5762G	interferon alfa-2a 9 million international units/0.5 mL injection, 1 x 0.5 mL syringe	30	5	..	*2681.40	Roferon-A	RO

INTERFERON ALFA-2B

Authority required (STREAMLINED)

3384

Adjunctive therapy of malignant melanoma following surgery in patients with nodal involvement

Authority required (STREAMLINED)

3382

Use in the treatment of Philadelphia chromosome positive myelogenous leukaemia in the chronic phase

Authority required (STREAMLINED)

3961

Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria:

(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;

(2) Evidence of chronic liver injury as determined by:

(a) Confirmed elevated serum ALT; or

(b) Liver biopsy

Authority required (STREAMLINED)

3962

Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy

Caution

Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

5768N	interferon alfa-2b 10 million international units/mL injection, 5 x 1 mL vials	3	5	..	*1489.50	Intron A	MK
5763H	interferon alfa-2b 18 million international units/1.2 mL injection, 1 x 1.2 mL cartridge	2	5	..	*357.48	Intron A Redipen	MK
5766L	interferon alfa-2b 18 million international units/3 mL injection, 1 x 3 mL vial	15	5	..	*2681.10	Intron A	MK
5767M	interferon alfa-2b 25 million international units/2.5 mL injection, 1 x 2.5 mL vial	15	5	..	*3723.75	Intron A	MK
5764J	interferon alfa-2b 30 million international units/1.2 mL injection, 1 x 1.2 mL cartridge	2	5	..	*595.80	Intron A Redipen	MK
5765K	interferon alfa-2b 60 million international units/1.2 mL injection, 1 x 1.2 mL cartridge	2	5	..	*1191.60	Intron A Redipen	MK

INTERFERON GAMMA-1B

Authority required (STREAMLINED)

3385

Treatment of chronic granulomatous disease in patients with frequent and severe infections despite adequate prophylaxis with antimicrobial agents

5769P	interferon gamma-1b 2 million international units (100 microgram/0.5 mL) injection, 6 x 0.5 mL vials	2	11	..	*2721.80	Imukin	BY

PEGINTERFERON ALFA-2A

Authority required (STREAMLINED)

3977

Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B without cirrhosis who satisfies all of the following criteria:

(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer	
					Price for Max. Qty \$		
	(2) Evidence of chronic liver injury as determined by:						
	(a) Confirmed elevated serum ALT; or						
	(b) Liver biopsy;						
	(3) Has received no prior peginterferon alfa therapy for the treatment of hepatitis B						
	<u>Authority required (STREAMLINED)</u>						
	3978						
	Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B with cirrhosis who has detectable HBV DNA.						
	Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.						
	Treatment is limited to 1 course of treatment for a duration of up to 48 weeks						
	<u>Authority required (STREAMLINED)</u>						
	3412						
	Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no prior interferon alfa or peginterferon alfa treatment for hepatitis C and have a contraindication to ribavirin, who satisfy all of the following criteria:						
	(1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive);						
	(2) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.						
	The treatment course is limited to up to 48 weeks.						
	Patients may only continue treatment after the first 12 weeks if the result of an HCV RNA quantitative assay (performed at the same laboratory using the same test) shows that the plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop						
	<u>Caution</u>						
	Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.						
	<u>Note</u>						
	Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:						
	(a) a nurse educator/counsellor for patients; and						
	(b) 24 hour access by patients to medical advice; and						
	(c) an established liver clinic; and						
	(d) facilities for safe liver biopsy.						
9515T	peginterferon alfa-2a 135 microgram/0.5 mL injection, 4 x 0.5 mL syringes	2	5	..	*2331.80	Pegasys	RO
9516W	peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes	2	5	..	*2700.46	Pegasys	RO

PEGINTERFERON ALFA-2A (&) RIBAVIRIN

Authority required (STREAMLINED)

4184

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease,

AND

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir; OR

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir; OR

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with simeprevir,

AND

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	simeprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at week 4; OR The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapsers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis; OR The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL,					
	AND The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,					
	AND The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,					
	AND The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,					
	AND The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,					
	AND The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,					
	AND The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,					
	AND The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL,					
	AND The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,					
	AND The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.					
	Population criteria: Patient must be aged 18 years or older,					
	AND Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.					
	Treatment criteria: Must be treated in an accredited treatment centre. Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.					
	Note No increase in the maximum quantity or number of units may be authorised.					
	Note No increase in the maximum number of repeats may be authorised.					
	Note Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C: (a) a nurse educator/counsellor for patients; and					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
	(b) 24-hour access by patients to medical advice; and (c) an established liver clinic.						
	<u>Authority required (STREAMLINED)</u>						
	4197						
	Chronic genotype 1 hepatitis C infection						
	Clinical criteria:						
	Patient must have compensated liver disease,						
	AND						
	Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,						
	AND						
	The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR						
	The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR						
	The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and in whom plasma HCV RNA is undetectable by an HCV RNA quantitative assay at week 4; OR						
	The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR						
	The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR						
	The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis; OR						
	The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and for whom the results of an HCV RNA qualitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL,						
	AND						
	The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,						
	AND						
	The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,						
	AND						
	The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,						
	AND						
	The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,						
	AND						
	The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,						
	AND						
	The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL,						
	AND						
	The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,						
	AND						
	The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.						
	Population criteria:						
	Patient must be aged 18 years or older,						
	AND						
	Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.						

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty	\$	

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

- (a) a nurse educator/counsellor for patients; and
- (b) 24-hour access by patients to medical advice; and
- (c) an established liver clinic.

Authority required (STREAMLINED)

4206

Chronic non-genotype 1 hepatitis C infection

Clinical criteria:

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

AND

Patient must have compensated liver disease,

AND

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

AND

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

AND

The treatment must be limited to a maximum duration of 48 weeks,

AND

The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

Population criteria:

Patient must be aged 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

- (a) a nurse educator/counsellor for patients; and
- (b) 24-hour access by patients to medical advice; and
- (c) an established liver clinic.

Authority required (STREAMLINED)

4187

Chronic non-genotype 1 hepatitis C infection

Clinical criteria:

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty	\$	
	The treatment must be the sole PBS-subsidised treatment for hepatitis C,						
	AND						
	Patient must have compensated liver disease,						
	AND						
	Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,						
	AND						
	The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,						
	AND						
	The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR						
	The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR						
	The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis,						
	AND						
	The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,						
	AND						
	The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.						
	Population criteria:						
	Patient must be aged 18 years or older,						
	AND						
	Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.						
	Treatment criteria:						
	Must be treated in an accredited treatment centre.						
	Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.						
	For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.						
	For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.						
	For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.						
	For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.						
	Caution						
	Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.						
	Caution						
	Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.						
	Note						
	Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:						
	(a) a nurse educator/counsellor for patients; and						
	(b) 24-hour access by patients to medical advice; and						
	(c) an established liver clinic.						
9524G	peginterferon alfa-2a 135 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [168 tablets], 1 pack	2	5	..	*3072.84	Pegasys RBV	RO
9525H	peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [112 tablets], 1 pack	2	5	..	*3085.28	Pegasys RBV	RO
9526J	peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [140 tablets], 1 pack	2	5	..	*3245.82	Pegasys RBV	RO
9527K	peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [168 tablets], 1 pack	2	5	..	*3406.36	Pegasys RBV	RO

PEGINTERFERON ALFA-2B (&) RIBAVIRIN

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	
<u>Authority required (STREAMLINED)</u>						
4189						
Chronic genotype 1 hepatitis C infection						
Clinical criteria:						
The treatment must be the sole PBS-subsidised treatment for hepatitis C,						
AND						
Patient must have compensated liver disease,						
AND						
Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),						
AND						
Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,						
AND						
The treatment must be limited to a maximum duration of 48 weeks,						
AND						
The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.						
Population criteria:						
Patient must weigh at least 27 kg,						
AND						
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.						
Treatment criteria:						
Must be treated in an accredited treatment centre.						
Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.						
<u>Note</u>						
No increase in the maximum quantity or number of units may be authorised.						
<u>Note</u>						
No increase in the maximum number of repeats may be authorised.						
<u>Note</u>						
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:						
(a) a nurse educator/counsellor for patients; and						
(b) 24-hour access by patients to medical advice; and						
(c) an established liver clinic.						
<u>Authority required (STREAMLINED)</u>						
4198						
Chronic genotype 1 hepatitis C infection						
Clinical criteria:						
The treatment must be the sole PBS-subsidised treatment for hepatitis C,						
AND						
Patient must have compensated liver disease,						
AND						
Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,						
AND						
The treatment must be limited to a maximum duration of 48 weeks,						
AND						
The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop.						
Population criteria:						
Patient must weigh at least 27 kg,						
AND						
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.						

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	Treatment criteria:					
	Must be treated in an accredited treatment centre.					
	Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.					
	For patients who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.					
	Note					
	No increase in the maximum quantity or number of units may be authorised.					
	Note					
	No increase in the maximum number of repeats may be authorised.					
	Note					
	Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:					
	(a) a nurse educator/counsellor for patients; and					
	(b) 24-hour access by patients to medical advice; and					
	(c) an established liver clinic.					
	Authority required (STREAMLINED)					
4199	Chronic non-genotype 1 hepatitis C infection					
	Clinical criteria:					
	The treatment must be the sole PBS-subsidised treatment for hepatitis C,					
	AND					
	Patient must have compensated liver disease,					
	AND					
	The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,					
	AND					
	Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),					
	AND					
	Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,					
	AND					
	The treatment must be limited to a maximum duration of 48 weeks,					
	AND					
	The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.					
	Population criteria:					
	Patient must weigh at least 27 kg,					
	AND					
	Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.					
	Treatment criteria:					
	Must be treated in an accredited treatment centre.					
	Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.					
	Note					
	No increase in the maximum quantity or number of units may be authorised.					
	Note					
	No increase in the maximum number of repeats may be authorised.					
	Note					
	Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:					
	(a) a nurse educator/counsellor for patients; and					
	(b) 24-hour access by patients to medical advice; and					
	(c) an established liver clinic.					
	Authority required (STREAMLINED)					
4192	Chronic non-genotype 1 hepatitis C infection					
	Clinical criteria:					

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	The treatment must be the sole PBS-subsidised treatment for hepatitis C,					
	AND					
	Patient must have compensated liver disease,					
	AND					
	Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,					
	AND					
	The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,					
	AND					
	The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR					
	The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR					
	The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis,					
	AND					
	The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,					
	AND					
	The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.					
	Population criteria:					
	Patient must weigh at least 27 kg,					
	AND					
	Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.					
	Treatment criteria:					
	Must be treated in an accredited treatment centre.					
	Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.					
	For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.					
	For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.					
	For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.					
	For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.					
	Note					
	Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:					
	(a) a nurse educator/counsellor for patients; and					
	(b) 24-hour access by patients to medical advice; and					
	(c) an established liver clinic.					
	Authority required (STREAMLINED)					
	4184					
	Chronic genotype 1 hepatitis C infection					
	Clinical criteria:					
	Patient must have compensated liver disease,					
	AND					
	Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),					
	AND					
	Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir; OR					
	Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir; OR					
	Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with simeprevir,					
	AND					
	The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12;					

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	OR					
	The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR					
	The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at week 4; OR					
	The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR					
	The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapsers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR					
	The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis; OR					
	The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL,					
	AND					
	The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,					
	AND					
	The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,					
	AND					
	The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,					
	AND					
	The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,					
	AND					
	The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,					
	AND					
	The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,					
	AND					
	The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL,					
	AND					
	The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,					
	AND					
	The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.					
	Population criteria:					
	Patient must be aged 18 years or older,					
	AND					
	Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.					
	Treatment criteria:					
	Must be treated in an accredited treatment centre.					
	Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.					
	Note					
	No increase in the maximum quantity or number of units may be authorised.					
	Note					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

No increase in the maximum number of repeats may be authorised.

Note

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

- (a) a nurse educator/counsellor for patients; and
- (b) 24-hour access by patients to medical advice; and
- (c) an established liver clinic.

Authority required (STREAMLINED)

4197

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease,

AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

AND

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and in whom plasma HCV RNA is undetectable by an HCV RNA quantitative assay at week 4; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and for whom the results of an HCV RNA qualitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	
	Patient must be aged 18 years or older,					
	AND					
	Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.					
	Treatment criteria:					
	Must be treated in an accredited treatment centre.					
	Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.					
	For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.					
	<u>Note</u>					
	No increase in the maximum quantity or number of units may be authorised.					
	<u>Note</u>					
	No increase in the maximum number of repeats may be authorised.					
	<u>Note</u>					
	Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:					
	(a) a nurse educator/counsellor for patients; and					
	(b) 24-hour access by patients to medical advice; and					
	(c) an established liver clinic.					
	<u>Authority required (STREAMLINED)</u>					
	4206					
	Chronic non-genotype 1 hepatitis C infection					
	Clinical criteria:					
	The treatment must be the sole PBS-subsidised treatment for hepatitis C,					
	AND					
	Patient must have compensated liver disease,					
	AND					
	The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,					
	AND					
	Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),					
	AND					
	Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,					
	AND					
	The treatment must be limited to a maximum duration of 48 weeks,					
	AND					
	The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.					
	Population criteria:					
	Patient must be aged 18 years or older,					
	AND					
	Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.					
	Treatment criteria:					
	Must be treated in an accredited treatment centre.					
	Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.					
	<u>Note</u>					
	No increase in the maximum quantity or number of units may be authorised.					
	<u>Note</u>					
	No increase in the maximum number of repeats may be authorised.					
	<u>Note</u>					
	Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:					
	(a) a nurse educator/counsellor for patients; and					
	(b) 24-hour access by patients to medical advice; and					
	(c) an established liver clinic.					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					Price for Max. Qty \$		
<u>Authority required (STREAMLINED)</u>							
4187							
Chronic non-genotype 1 hepatitis C infection							
Clinical criteria:							
The treatment must be the sole PBS-subsidised treatment for hepatitis C,							
AND							
Patient must have compensated liver disease,							
AND							
Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,							
AND							
The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,							
AND							
The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR							
The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR							
The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis,							
AND							
The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,							
AND							
The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.							
Population criteria:							
Patient must be aged 18 years or older,							
AND							
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.							
Treatment criteria:							
Must be treated in an accredited treatment centre.							
Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.							
For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.							
For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.							
For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.							
For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.							
<u>Caution</u>							
Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.							
<u>Caution</u>							
Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.							
<u>Note</u>							
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:							
(a) a nurse educator/counsellor for patients; and							
(b) 24-hour access by patients to medical advice; and							
(c) an established liver clinic.							
9534T	peginterferon alfa-2b 100 microgram injection [4 x 100 microgram cartridges] (&) ribavirin 200 mg capsule [112 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack	2	5	..	*3099.62	Pegatron	MK
9529M	peginterferon alfa-2b 50 microgram injection [4 x 50 microgram cartridges] (&) ribavirin 200 mg capsule [112 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack	2	5	..	*2119.74	Pegatron	MK
9530N	peginterferon alfa-2b 80 microgram injection [4 x 80	2	5	..	*2422.72	Pegatron	MK

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	
	microgram cartridges] (&) ribavirin 200 mg capsule [84 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack					

PEGINTERFERON ALFA-2B (&) RIBAVIRIN

Authority required (STREAMLINED)

4184

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease,

AND

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir; OR

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir; OR

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with simeprevir,

AND

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at week 4; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapsers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

AND

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL,					
	AND					
	The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,					
	AND					
	The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.					
	Population criteria:					
	Patient must be aged 18 years or older,					
	AND					
	Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.					
	Treatment criteria:					
	Must be treated in an accredited treatment centre.					
	Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.					
	Note					
	No increase in the maximum quantity or number of units may be authorised.					
	Note					
	No increase in the maximum number of repeats may be authorised.					
	Note					
	Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:					
	(a) a nurse educator/counsellor for patients; and					
	(b) 24-hour access by patients to medical advice; and					
	(c) an established liver clinic.					
	Authority required (STREAMLINED)					
	4197					
	Chronic genotype 1 hepatitis C infection					
	Clinical criteria:					
	Patient must have compensated liver disease,					
	AND					
	Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,					
	AND					
	The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR					
	The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR					
	The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and in whom plasma HCV RNA is undetectable by an HCV RNA quantitative assay at week 4; OR					
	The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR					
	The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR					
	The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis; OR					
	The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and for whom the results of an HCV RNA qualitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL,					
	AND					
	The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,					
	AND					
	The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	
	qualitative assay at week 24, AND The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL, AND The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL, AND The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24. Population criteria: Patient must be aged 18 years or older, AND Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age. Treatment criteria: Must be treated in an accredited treatment centre. Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records. For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary. Note No increase in the maximum quantity or number of units may be authorised. Note No increase in the maximum number of repeats may be authorised. Note Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C: (a) a nurse educator/counsellor for patients; and (b) 24-hour access by patients to medical advice; and (c) an established liver clinic. Authority required (STREAMLINED) 4206 Chronic non-genotype 1 hepatitis C infection Clinical criteria: The treatment must be the sole PBS-subsidised treatment for hepatitis C, AND Patient must have compensated liver disease, AND The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C, AND Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated), AND Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C, AND The treatment must be limited to a maximum duration of 48 weeks,					

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	AND					
	The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.					
	Population criteria:					
	Patient must be aged 18 years or older,					
	AND					
	Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.					
	Treatment criteria:					
	Must be treated in an accredited treatment centre.					
	Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.					
	Note					
	No increase in the maximum quantity or number of units may be authorised.					
	Note					
	No increase in the maximum number of repeats may be authorised.					
	Note					
	Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:					
	(a) a nurse educator/counsellor for patients; and					
	(b) 24-hour access by patients to medical advice; and					
	(c) an established liver clinic.					
	Authority required (STREAMLINED)					
	4187					
	Chronic non-genotype 1 hepatitis C infection					
	Clinical criteria:					
	The treatment must be the sole PBS-subsidised treatment for hepatitis C,					
	AND					
	Patient must have compensated liver disease,					
	AND					
	Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,					
	AND					
	The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,					
	AND					
	The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR					
	The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR					
	The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis,					
	AND					
	The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,					
	AND					
	The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.					
	Population criteria:					
	Patient must be aged 18 years or older,					
	AND					
	Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.					
	Treatment criteria:					
	Must be treated in an accredited treatment centre.					
	Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.					
	For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.					
	For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					Price for Max. Qty \$		
For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.							
For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.							
Caution							
Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.							
Caution							
Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.							
Note							
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:							
(a) a nurse educator/counsellor for patients; and							
(b) 24-hour access by patients to medical advice; and							
(c) an established liver clinic.							
9536X	peginterferon alfa-2b 120 microgram injection [4 x 120 microgram cartridges] (&) ribavirin 200 mg capsule [140 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack	2	5	..	*3491.58	Pegatron	MK
9538B	peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (&) ribavirin 200 mg capsule [140 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack	2	5	..	*4079.52	Pegatron	MK
9539C	peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (&) ribavirin 200 mg capsule [168 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack	2	5	..	*4079.52	Pegatron	MK
9540D	peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (&) ribavirin 200 mg capsule [196 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack	2	5	..	*4364.48	Pegatron	MK
9531P	peginterferon alfa-2b 80 microgram injection [4 x 80 microgram cartridges] (&) ribavirin 200 mg capsule [140 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack	2	5	..	*2707.66	Pegatron	MK

Other immunostimulants

PLERIXAFOR

Authority required (STREAMLINED)

4549

Mobilisation of haematopoietic stem cells

Clinical criteria:

The treatment must be in combination with granulocyte-colony stimulating factor (G-CSF),

AND

Patient must have lymphoma; OR

Patient must have multiple myeloma,

AND

Patient must require autologous stem cell transplantation,

AND

Patient must have failed previous stem cell collection; OR

Patient must be undergoing chemotherapy plus G-CSF mobilisation and their peripheral blood CD34+ count is less than 10,000 per millilitre or less than 10 million per litre on the day of planned collection; OR

Patient must be undergoing chemotherapy plus G-CSF mobilisation and the first apheresis has yielded less than 1 million CD34+ cells/kg.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records.

Note

Applications for increased maximum quantities will only be authorised for patients with body weight greater than 100 kg.

10083Q	plerixafor 24 mg/1.2 mL injection: subcutaneous infusion, 1 x 1.2 mL vial	1	1	..	6991.00	Mozobil	GZ

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					\$	\$	

IMMUNOSUPPRESSANTS

IMMUNOSUPPRESSANTS

Selective immunosuppressants

ABATACEPT

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have severe active rheumatoid arthritis,

AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months,

AND

Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times,

AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly,

AND

Patient must not receive more than 16 weeks of treatment under this restriction,

AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	

(3) a signed patient acknowledgement.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 4 repeats will be authorised.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;

(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;

(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note

Special Pricing Arrangements apply.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
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supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis,

AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy,

AND

Patient must not receive more than 16 weeks of treatment under this restriction,

AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	Population criteria: Patient must be aged 18 years or older. Treatment criteria: Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 4 repeats will be authorised. Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased. Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to a treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 HOBART TAS 7001 Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept). Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time. In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist. A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements: - a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					\$	\$	

- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment,

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	<u>Authority required</u> Severe active rheumatoid arthritis Treatment Phase: Continuing treatment. Clinical criteria: Patient must have a documented history of severe active rheumatoid arthritis, AND Patient must have demonstrated an adequate response to treatment with this drug, AND Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction, AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Population criteria: Patient must be aged 18 years or older. Treatment criteria: Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 5 repeats will be authorised. All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. <u>Note</u> Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					Qty \$	

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment,

AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty	\$	
	Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.						
	Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001						
5605B	abatacept 250 mg injection, 1 x 250 mg vial	1	..	..	504.43		Orencia
							BQ

ECULIZUMAB

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing treatment – New patient

Clinical criteria:

Patient must have received 24 weeks therapy under the initial restriction with PBS subsidised eculizumab for this condition,

AND

Patient must have demonstrated on-going treatment response of PBS-subsidised eculizumab treatment for this condition,

AND

Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Treatment criteria:

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure .

A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					Price for Max. Qty \$	

The authority application must be in writing and must include:

- (1) A completed authority prescription form; and
- (2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and
- (3) A copy of a current Certificate of vaccination; and
- (4) A measurement of body weight at the time of application; and
- (5) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application ; and
- (6) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
- (7) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

Note

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).

Note

Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note

WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis)

> Vaccinate patients with a meningococcal vaccine at least 2 weeks prior to receiving the first dose of eculizumab; revaccinate according to current medical guidelines for vaccine use

> Patients less than 2 years of age and those who are treated with eculizumab less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination. Monitor patients

for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing treatment – beyond initial 48 weeks of treatment

Clinical criteria:

Patient must have received 48 weeks of treatment under Initial treatment-New patient, Initial treatment-Balance of supply and Continuing treatment-New patient with PBS-subsidised eculizumab for this condition,

AND

Patient must have demonstrated on-going treatment response with PBS-subsidised eculizumab for this condition,

AND

Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition,

AND

Patient must have a TMA-related cardiomyopathy as evidenced by left ventricular ejection fraction < 40%; OR

Patient must have severe TMA-related neurological impairment; OR

Patient must have severe TMA-related gastrointestinal impairment; OR

Patient must have severe TMA-related pulmonary impairment; OR

Patient must have grade 4 or 5 chronic kidney disease (eGFR of less than 30 ml/min),

AND

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					\$	\$	

Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with ecilizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with ecilizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised ecilizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. This will assist DHS in the consideration of the patient's eligibility for further PBS subsidised treatment.

The authority application must be in writing and must include:

- (1) A completed authority prescription form; and
- (2) A completed aHUS ecilizumab Authority Application Supporting Information Form for Continuing treatment; and
- (3) A copy of a current Certificate of vaccination; and
- (4) A measurement of body weight at the time of application; and
- (5) A supporting statement with clinical evidence of severe TMA-related cardiomyopathy (including current LVEF result), neurological impairment, gastrointestinal impairment or pulmonary impairment; and
- (6) Evidence that the patient has had a treatment response including haematological results of no more than 1 month old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 month old at the time of application; and
- (7) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing ecilizumab is severe extra-renal complications that have significantly improved; and
- (8) If the indication for continuing ecilizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

Note

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).

Note

Applications for treatment with ecilizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note

WARNING: Ecilizumab increases the risk of meningococcal infections (septicaemia and/or meningitis)

> Vaccinate patients with a meningococcal vaccine at least 2 weeks prior to receiving the first dose of ecilizumab; revaccinate according to current

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
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	medical guidelines for vaccine use						

> Patients less than 2 years of age and those who are treated with eculizumab less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination. Monitor patients

for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment 2 – Recommencement of treatment after an initial 48-week period

Clinical criteria:

Patient must have demonstrated treatment response to previous 48 weeks of treatment with PBS-subsidised eculizumab for this condition,

AND

Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition,

AND

Patient must have the following clinical conditions: (i) either significant haemolysis as measured by low/absent haptoglobin; or presence of schistocytes on the blood film; or lactate dehydrogenase (LDH) above normal; AND (ii) either platelet consumption as measured by either 25% decline from patient baseline or thrombocytopenia (platelet count $<150 \times 10^9/L$); OR (iii) TMA-related organ impairment including on recent biopsy,

AND

Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. This will assist DHS in the consideration of the patient's eligibility for further PBS subsidised treatment.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					Price for Max.	Qty	
					\$	\$	

The authority application must be in writing and must include:

- (1) A completed authority prescription form(s); and
- (2) A completed aHUS eculizumab Authority Application Supporting Information Form for Initial treatment 2- Recommencement of treatment after an initial 48-week period; and
- (3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and
- (4) A copy of a current Certificate of vaccination; and
- (5) A measurement of body weight at the time of application, and
- (6) A supporting statement with clinical evidence of TMA-related organ damage including current (within one week of application) haematological results (platelet count, haptoglobin and LDH), eGFR level, and, if applicable, on recent biopsy;
- (7) Evidence that the patient has had a treatment response to their previous treatment with eculizumab ; and
- (8) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
- (9) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

Note

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).

Note

Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note

A raise in LDH alone is not a sufficient reason to re-commence eculizumab, but thrombocytopenia with one marker of haemolysis (such as raised LDH, presence of schistocytes, or low/absence of haptoglobin) is an accepted reason to consider re-commencement of eculizumab treatment.

Note

Kidney transplantation/dialysis is not a contraindication to recommencement of eculizumab treatment.

Note

WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis)

> Vaccinate patients with a meningococcal vaccine at least 2 weeks prior to receiving the first dose of eculizumab; revaccinate according to current medical guidelines for vaccine use

> Patients less than 2 years of age and those who are treated with eculizumab less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination. Monitor patients

for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing treatment – following recommencement of treatment after an initial 48-week period

Clinical criteria:

Patient must have received Initial treatment 2-recommencement of treatment after an initial 48-week period with PBS-subsidised eculizumab for this condition,

AND

Patient must have demonstrated ongoing treatment response to the previous 24 weeks of PBS-subsidised eculizumab for this condition,

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					Price for Max. Qty \$	

AND

Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition,

AND

Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. This will assist DHS in the consideration of the patient's eligibility for further PBS subsidised treatment.

The authority application must be in writing and must include:

- (1) A completed authority prescription form; and
- (2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and
- (3) A copy of a current Certificate of vaccination; and
- (4) A measurement of body weight at the time of application; and
- (5) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and
- (6) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
- (7) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

Note

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).

Note

Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note

WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis)

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max. Qty \$		
	> Vaccinate patients with a meningococcal vaccine at least 2 weeks prior to receiving the first dose of eculizumab; revaccinate according to current medical guidelines for vaccine use						

> Patients less than 2 years of age and those who are treated with eculizumab less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination. Monitor patients

for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial 3 - Grandfather eculizumab patients

Clinical criteria:

Patient must have had documented history of active and progressing thrombotic microangiopathy (TMA),

AND

Patient must have had documented an ADAMTS-13 activity level consistent with a diagnosis of aHUS,

AND

Patient must have received treatment with eculizumab for this condition prior to 1 December 2014,

AND

Patient must have received treatment with eculizumab within the last 6 months at the time of application,

AND

Patient must have demonstrated on-going treatment response as specified in the Continuing treatment New Patient criteria for PBS-subsidised treatment with eculizumab for this condition, if the patient has received adequate therapy in order to demonstrate response,

AND

Patient must not have experienced treatment failure with eculizumab for this condition as specified in the Continuing treatment New Patient criteria for PBS-subsidised treatment with eculizumab for this condition,

AND

Patient must have clinical features of active organ damage or impairment at the time of a diagnosis of aHUS episode that required treatment with eculizumab,

AND

Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

Evidence of active and progressing TMA is defined by the following:

(1) a platelet count of less than $150 \times 10^9/L$; and evidence of two of the following:

(i) presence of schistocytes on blood film;

(ii) low or absent haptoglobin;

(iii) lactate dehydrogenase (LDH) above normal range;

OR

(2) tissue biopsy confirming TMA in patients who don't have evidence of platelet consumption and haemolysis;

AND

(3) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:

(a) kidney impairment as demonstrated by one of the following:

(i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or

(ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or

(iii) a sCr of greater than the age-appropriate ULN in paediatric patients; or

(iv) a renal biopsy

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.	Brand Name and Manufacturer
					Qty \$	

- (b) onset of TMA-related neurological impairment;
- (c) onset of TMA-related cardiac impairment;
- (d) onset of TMA-related gastrointestinal impairment;
- (e) onset of TMA-related pulmonary impairment

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must be in writing and must include:

- (1) A completed authority prescription form; and
 - (2) A completed aHUS eculizumab Authority Application Supporting Information Form for initial PBS-subsidised eculizumab treatment; and
 - (3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and
 - (4) A copy of a current Certificate of vaccination; and
 - (5) A measurement of body weight at the time of application; and
 - (6) The result of ADAMTS-13 activity on a blood sample at the time this condition was diagnosed; and
 - (7) Evidence that the patient has previously received treatment with eculizumab for this condition within the last 6 months at the time of application; and
 - (8) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; or clinical reasons to justify the commencing of treatment with PBS-subsidised eculizumab; and
 - (9) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
 - (10) A confirmed negative STEC (Shiga toxin-producing E.Coli) result if available at the time of diagnosis; or evidence that the diagnosis was not associated with an infection; and
 - (11) Where available in the week prior to commencing eculizumab results demonstrating:
 - (a) a platelet count of less than $150 \times 10^9/L$; and evidence of two of the following:
 - (i) presence of schistocytes on blood film;
 - (ii) low or absent haptoglobin;
 - (iii) lactate dehydrogenase (LDH) above normal range;
 - OR
 - (b) tissue biopsy confirming TMA in patients who don't have evidence of platelet consumption and haemolysis;
- AND
- (c) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:
- (a) kidney impairment as demonstrated by one of the following:
 - (i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.	Brand Name and Manufacturer
					Qty \$	
	(ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or (iii) a sCr of greater than the age-appropriate ULN in paediatric patients ; or (iv) a renal biopsy (b) onset of TMA-related neurological impairment; (c) onset of TMA-related cardiac impairment; (d) onset of TMA-related gastrointestinal impairment; (e) onset of TMA-related pulmonary impairment ; and (12) Where available within one month prior to commencement of eculizumab, evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records.					

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. This will assist DHS in the consideration of the patient's eligibility for further PBS subsidised treatment.

Note

WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis)

> Vaccinate patients with a meningococcal vaccine at least 2 weeks prior to receiving the first dose of eculizumab; revaccinate according to current medical guidelines for vaccine use

> Patients less than 2 years of age and those who are treated with eculizumab less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination. Monitor patients

for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

10183Y	eculizumab 300 mg/30 mL injection, 1 x 30 mL vial	1	5	..	5937.50	Soliris	XI

ECULIZUMAB

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment 1 – New patient – Balance of Supply

Clinical criteria:

Patient must have received PBS-subsidised initial supply of eculizumab for this condition,

AND

Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample,

AND

Patient must not receive more than 20 weeks supply under this restriction.

Treatment criteria:

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

ADAMTS-13 activity result must have been submitted to the Department of Human Services. In the case that a sample for ADAMTS-13 activity taken prior to plasma exchange or infusion was not available at the time of application for Initial Treatment 1 New Patient, ADAMTS-13 activity must have been measured 1-2 weeks following the last plasma exchange or infusion, and must have been submitted to the Department of Human Services within 27 days of commencement of eculizumab. The date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of the last, if any, plasma exchange or infusion that was undertaken in the two weeks prior to collection of the ADAMTS-13 assay must also have been provided to Department of Human Services.

Note

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. This will assist DHS in the consideration of the patient's eligibility for further PBS subsidised treatment

Note

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 4 repeats, according to the specified dosage in the approved Product Information (PI).

Note

Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

10190H	eculizumab 300 mg/30 mL injection, 1 x 30 mL vial	1	4	..	5937.50	Soliris	XI

ECULIZUMAB

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment 1 – New patient

Clinical criteria:

Patient must have active and progressing thrombotic microangiopathy (TMA),

AND

Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample taken prior to plasma exchange or infusion; or, if ADAMTS-13 activity was not collected prior to plasma exchange or infusion, patient must have platelet counts of greater than $30 \times 10^9/L$ and a serum creatinine of greater than 150 mol/L,

AND

Patient must have a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days,

AND

Patient must have clinical features of active organ damage or impairment,

AND

Patient must not receive more than 4 weeks of treatment under this restriction.

Treatment criteria:

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

Evidence of active and progressing TMA is defined by the following:

(1) a platelet count of less than $150 \times 10^9/L$; and evidence of two of the following:

(i) presence of schistocytes on blood film;

(ii) low or absent haptoglobin;

(iii) lactate dehydrogenase (LDH) above normal range;

OR

(2) tissue biopsy confirming TMA in patients who don't have evidence of platelet consumption and haemolysis;

AND

(3) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:

(a) kidney impairment as demonstrated by one of the following:

(i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or

(ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or

(iii) a sCr of greater than the age-appropriate ULN in paediatric patients; or

(iv) a renal biopsy

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	(b) onset of TMA-related neurological impairment; (c) onset of TMA-related cardiac impairment; (d) onset of TMA-related gastrointestinal impairment; (e) onset of TMA-related pulmonary impairment The authority application must be in writing and must include: (1) A completed authority prescription form; and (2) A completed aHUS eculizumab Authority Application Supporting Information Form- Initial PBS-subsidised eculizumab treatment; and (3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and (4) A copy of a current Certificate of vaccination; and (5) A measurement of body weight at the time of application; and (6) The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion; the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the two weeks prior to collection of the ADAMTS-13 assay; and (7) In the case that a sample for ADAMTS-13 assay was not collected prior to plasma exchange or infusion, measurement of ADAMTS-13 activity must be taken 1-2 weeks following the last plasma exchange or infusion. The ADAMTS-13 result must be submitted to the Department of Human Services within 27 days of commencement of eculizumab treatment in order for the patient to be considered as eligible for further PBS-subsidised eculizumab treatment, under Initial treatment 1-balance of supply; and (8) A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days; and (9) Evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records. All tests must have been performed within one month of application; and (10) For all patients, a recent measurement of eGFR, platelets and two of either LDH, haptoglobin or schistocytes of no more than 1 week old at the time of application. Note Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. This will assist DHS in the consideration of the patient s eligibility for further PBS subsidised treatment Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for four weeks of treatment, according to the specified dosage in the approved Product Information (PI) Note Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved. Note WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis) > Vaccinate patients with a meningococcal vaccine at least 2 weeks prior to receiving the first dose of eculizumab; revaccinate according to current medical guidelines for vaccine use > Patients less than 2 years of age and those who are treated with eculizumab less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination. Monitor patients for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary. Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.					
10191J	eculizumab 300 mg/30 mL injection, 1 x 30 mL vial	1	..	..	5937.50	Soliris

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer	
					Price for Max. Qty \$		
EVEROLIMUS							
<u>Authority required (STREAMLINED)</u>							
3355							
Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required							
<u>Authority required (STREAMLINED)</u>							
3356							
Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of cardiac allograft rejection. Management includes initiation, stabilisation and review of therapy as required							
<u>Caution</u>							
Careful monitoring of patients is mandatory.							
5737Y	everolimus 1 mg tablet, 60	4	5	..	*3844.80	Certican	NV
5738B	everolimus 250 microgram tablet, 60	2	5	..	*480.60	Certican	NV
5739C	everolimus 500 microgram tablet, 60	2	5	..	*961.20	Certican	NV
5740D	everolimus 750 microgram tablet, 60	4	5	..	*2883.60	Certican	NV
MYCOPHENOLATE							
<u>Authority required (STREAMLINED)</u>							
4084							
Prophylaxis of renal allograft rejection							
Treatment Phase: Management							
Clinical criteria:							
The treatment must be under the supervision and direction of a transplant unit.							
<u>Authority required (STREAMLINED)</u>							
4095							
WHO Class III, IV or V lupus nephritis							
Treatment Phase: Management							
Clinical criteria:							
The condition must be proven by biopsy.							
Treatment criteria:							
Must be treated by a nephrologist or in consultation with a nephrologist.							
The name of the consulting nephrologist must be included in the patient medical records.							
<u>Caution</u>							
Careful monitoring of patients is mandatory.							
<u>Note</u>							
Management includes initiation, stabilisation and review of therapy as required.							
9503E	mycophenolate 180 mg tablet: enteric, 120 tablets	2	5	..	*217.62	Myfortic	NV
9504F	mycophenolate 360 mg tablet: enteric, 120 tablets	2	5	..	*435.22	Myfortic	NV
MYCOPHENOLATE							
<u>Authority required (STREAMLINED)</u>							
3355							
Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required							
<u>Authority required (STREAMLINED)</u>							
3356							
Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of cardiac allograft rejection. Management includes initiation, stabilisation and review of therapy as required							
<u>Caution</u>							
Careful monitoring of patients is mandatory.							
<u>Note</u>							
For item codes 9501C and 1839T, pharmaceutical benefits that have the form capsule 250 mg are equivalent for the purposes of substitution.							
1839T	mycophenolate Capsule 250 mg, 50	12	5	..	*544.08 ^a	Ceptolate	AF

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer	
					Qty	\$		
9501C	mycophenolate mofetil 250 mg capsule, 100	6	5	..	*544.08		^a APO-Mycophenolate	TX
							^a CellCept	RO
							^a Mycophenolate Sandoz	SZ
							^a Pharmacor	CR
							Mycophenolate 250	

MYCOPHENOLATE

Authority required (STREAMLINED)

3355

Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required

Authority required (STREAMLINED)

3356

Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of cardiac allograft rejection. Management includes initiation, stabilisation and review of therapy as required

Caution

Careful monitoring of patients is mandatory.

9500B	mycophenolate mofetil 1 g/5 mL oral liquid: powder for, 165 mL	2	5	..	*489.02		CellCept	RO
9502D	mycophenolate mofetil 500 mg tablet, 50	6	5	..	*544.02		^a APO-Mycophenolate	TX
							^a CellCept	RO
							^a Ceptolate	AF
							^a Mycophenolate Sandoz	SZ
							^a Pharmacor	CR
							Mycophenolate 500	

NATALIZUMAB

Authority required (STREAMLINED)

3425

Treatment, as monotherapy, by a neurologist, of clinically definite relapsing-remitting multiple sclerosis in an ambulatory (without assistance or support) patient 18 years of age or older, who has experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years.

The diagnosis must be confirmed by magnetic resonance imaging of the brain and/or spinal cord and the date of the scan included in the patient's medical notes, unless written certification provided by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient is included in the patient's medical notes.

Natalizumab must be ceased if there is continuing progression of disability while on treatment with natalizumab. For continued treatment the patient must demonstrate compliance with, and an ability to tolerate, natalizumab

Caution

Progressive multifocal leukoencephalopathy has been reported with this drug.

Note

Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.

Note

Special Pricing Arrangements apply.

9505G	natalizumab 300 mg/15 mL injection, 1 x 15 mL vial	1	5	..	1568.04		Tysabri	BD

SIROLIMUS

Authority required (STREAMLINED)

3355

Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required

Caution

Careful monitoring of patients is mandatory.

9549N	sirolimus 1 mg tablet, 100	2	5	..	*1446.66		Rapamune	PF
9550P	sirolimus 1 mg/mL oral liquid, 60 mL	2	5	..	*936.00		Rapamune	PF
9548M	sirolimus 2 mg tablet, 100	2	5	..	*2893.34		Rapamune	PF
9747B	sirolimus 500 microgram tablet, 100	2	5	..	*723.34		Rapamune	PF

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

Tumor necrosis factor alpha (TNF-) inhibitors

ADALIMUMAB

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

Clinical criteria:

Patient must have severe active juvenile idiopathic arthritis,

AND

Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition;
OR

Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months,

AND

Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR

Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty	\$	

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and
- (3) an acknowledgement signed by a parent or authorised guardian.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

Note

Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course. (b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. (2) Swapping therapy. Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months. A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing. (3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement. (4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy. A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction. (5) Withdrawal of treatment after sustained remission. Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased. <u>Authority required</u> Severe active juvenile idiopathic arthritis Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months) Clinical criteria: Patient must have a documented history of severe active juvenile idiopathic arthritis, AND Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, AND Patient must not have failed PBS-subsidised therapy with adalimumab for this condition in the current treatment cycle, AND Patient must not receive more than 16 weeks of treatment under this restriction. Population criteria: Patient must be under 18 years of age. Treatment criteria: Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	
For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.						

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with adalimumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised adalimumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.					
	A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.					
	A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.					
	A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.					
	There is no limit to the number of treatment cycles a patient may undertake.					
	(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.					
	(a) Initial treatment.					
	Applications for initial treatment should be made where:					
	(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or					
	(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or					
	(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or					
	(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).					
	Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.					
	A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.					
	Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.					
	For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.					
	(b) Continuing treatment.					
	Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.					
	It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.					
	Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.					
	Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.					
	(2) Swapping therapy.					
	Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.					
	A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.					
	To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.					
	To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.					
	(3) Baseline measurements to determine response.					
	The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.					
	(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.					
	A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.					
	(5) Withdrawal of treatment after sustained remission.					
	Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					Qty	\$	

ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply

Clinical criteria:

Patient must have received insufficient adalimumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient adalimumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment,

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis,

AND

Patient must have demonstrated an adequate response to treatment with adalimumab,

AND

Patient must have received adalimumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty \$		
Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.							

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

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HOBART TAS 7001

Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

- (1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

- (a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					Price for Max. Qty \$	

details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment – balance of supply

Clinical criteria:

Patient must have received insufficient adalimumab therapy under the Continuing treatment restriction to complete 24 weeks treatment,

AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.	Brand Name and Manufacturer	
					Qty \$		
	Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001						
9661L	adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes	1	..	..	1630.00	Humira	VE
9663N	adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges	1	..	..	1630.00	Humira	VE
9662M	adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes	1	..	..	1630.00	Humira	VE

ETANERCEPT

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

Clinical criteria:

Patient must have severe active juvenile idiopathic arthritis,

AND

Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; OR

Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months,

AND

Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR

Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and

(3) an acknowledgement signed by a parent or authorised guardian.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

Note

Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis,

AND

Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle,

AND

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					Price for Max.	Qty	
					\$	\$	

Patient must not have failed PBS-subsidised therapy with etanercept for this condition in the current treatment cycle,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be under 18 years of age.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with etanercept in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised etanercept treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

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Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab,

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	etanercept and tocilizumab only.					
	A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.					
	From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:					
	(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and					
	(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.					
	Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.					
	A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.					
	A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.					
	A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.					
	There is no limit to the number of treatment cycles a patient may undertake.					
	(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.					
	(a) Initial treatment.					
	Applications for initial treatment should be made where:					
	(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or					
	(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or					
	(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or					
	(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).					
	Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.					
	A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.					
	Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.					
	For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.					
	(b) Continuing treatment.					
	Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.					
	It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.					
	Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.					
	Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.					
	(2) Swapping therapy.					
	Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.					
	A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.					
	To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.					
	To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.					
	(3) Baseline measurements to determine response.					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					Price for Max.	Qty	
					\$	\$	

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply

Clinical criteria:

Patient must have received insufficient etanercept therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient etanercept therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment,

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

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Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis,

AND

Patient must have demonstrated an adequate response to treatment with etanercept,

AND

Patient must have received etanercept as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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	(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or					

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

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Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
	commence a further course of treatment within the same treatment cycle.						
	A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.						
	There is no limit to the number of treatment cycles a patient may undertake.						
	(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.						
	(a) Initial treatment.						
	Applications for initial treatment should be made where:						
	(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or						
	(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or						
	(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or						
	(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).						
	Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.						
	A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.						
	Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.						
	For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.						
	(b) Continuing treatment.						
	Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.						
	It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.						
	Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.						
	Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.						
	(2) Swapping therapy.						
	Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.						
	A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.						
	To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.						
	To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.						
	(3) Baseline measurements to determine response.						
	The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.						
	(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.						
	A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.						
	(5) Withdrawal of treatment after sustained remission.						
	Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.						

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment – balance of supply

Clinical criteria:

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer	
					Price for Max. Qty \$		
Patient must have received insufficient etanercept therapy under the Continuing treatment restriction to complete 24 weeks treatment, AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Treatment criteria: Must be treated by a rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001							
5735W	ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1	1	..	..	1630.01	Enbrel	PF
5733R	ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1	1	..	..	1630.01	Enbrel	PF
5734T	etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack	1	..	..	815.00	Enbrel	PF

INFLIXIMAB

Authority required (STREAMLINED)

4524

Acute severe ulcerative colitis

Clinical criteria:

Patient must have received an infusion of infliximab for the treatment of this condition as a hospital inpatient no more than two weeks prior to the date of the authority application,

AND

Patient must be an adult aged 18 years or older, and prior to initiation of infliximab treatment in hospital must have been experiencing six or more bloody stools per day, plus at least one of the following: (i) Temperature greater than 37.8 degrees Celsius; (ii) Pulse rate greater than 90 beats per minute; (iii) Haemoglobin less than 105 g/L; (iv) Erythrocyte sedimentation rate greater than 30 mm/h; OR

Patient must be a child aged 6 to 17 years inclusive, and prior to initiation of infliximab treatment in hospital must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) greater than or equal to 65, with the diagnosis confirmed by a gastroenterologist, or a consultant physician as specified below,

AND

Patient must have failed to achieve an adequate response to at least 72 hours treatment with intravenous corticosteroids prior to initiation of infliximab treatment in hospital.

Population criteria:

Patient must be 6 years of age or older.

Treatment criteria:

Must be treated by a gastroenterologist; OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology, or general medicine specialising in gastroenterology].

For adults aged 18 years or older, failure to achieve an adequate response to intravenous corticosteroid treatment is defined by the Oxford criteria where:

(i) If assessed on day 3, patients pass 8 or more stools per day or 3 or more stools per day with a C-reactive protein (CRP) greater than 45 mg/L

(ii) If assessed on day 7, patients pass 3 or more stools per day with visible blood.

For children aged 6 to 17 years, failure to achieve an adequate response to intravenous corticosteroids means a PUCAI score greater than 45 at 72 hours.

At the time of authority application, prescribers should request the appropriate number of vials, based on the weight of the patient, to provide

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	
	sufficient for a single infusion at a dose of 5 mg per kg.					

Before administering infliximab to a child aged 6 to 17 years, the treating clinician must have consulted with a paediatric gastroenterologist or with an institution experienced in performance of paediatric colectomy. The name of the specialist or institution must be included in the patient's medical records.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records.

Note

No increase in the maximum number of repeats may be authorised.

10067W	infliximab 100 mg injection, 1 x 100 mg vial	5	1	..	*3758.50	Remicade	JC

INFLIXIMAB

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment (new patient)

Clinical criteria:

Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more months or have intolerance necessitating permanent treatment withdrawal,

AND

Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR

Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR

Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal,

AND

Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR

Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR

Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

Population criteria:

Patient must be 6 years of age or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a paediatrician or specialist paediatric gastroenterologist if aged between 6 to 17 years.

Applications for authorisation of initial treatment must be in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and
 - (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
 - (iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment. The most recent Mayo clinic, partial Mayo clinic or PUCAI score must be no more than 1 month old at the time of application.

Patients who fail to achieve a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a PUCAI score less than 10 within the first 12 weeks of receiving this drug for ulcerative colitis, or have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or have failed to maintain a PUCAI score less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

A partial Mayo clinic or PUCAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The patient or guardian (required if patient aged 6 to 17 years) must have signed a patient acknowledgement indicating they understand and

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application.

Patients may qualify for PBS-subsidised treatment under this restriction once only.

Note

Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

Special Pricing Arrangements apply.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial PBS-subsidised treatment of moderate to severe ulcerative colitis in a patient who has previously received non-PBS-subsidised therapy with this drug (grandfather)

Clinical criteria:

Patient must have been receiving treatment with this drug prior to 1 December 2014,

AND

Patient must have had a Mayo clinic score greater than or equal to 6 prior to commencing treatment with this drug; OR

Patient must have had a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores were both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo score) prior to commencing treatment with this drug; OR

Patient must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 prior to commencing treatment with this drug; OR

Patient must have a documented history of moderate to severe refractory ulcerative colitis prior to having commenced treatment with this drug where a Mayo clinic, partial Mayo clinic or PUCAI baseline assessment is not available,

AND

Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR

Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years.

Population criteria:

Patient must be 6 years of age or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a paediatrician or specialist paediatric gastroenterologist if aged between 6 to 17 years.

Applications for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and baseline Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition and

(ii) the date of commencement of this drug and

(iii) the signed patient acknowledgement.

The current Mayo clinic or partial Mayo clinic or PUCAI assessment must be no more than 1 month old at the time of application. The baseline assessment must be from immediately prior to commencing treatment with this drug.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to be sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised. The patient or guardian (required if patient aged 6 to 17 years) must have signed a patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment. Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria. Note Where a baseline assessment is not available, please call the Department of Human Services on 1800 700 270 to discuss (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 Note Special Pricing Arrangements apply. Authority required Moderate to severe ulcerative colitis Treatment Phase: Balance of supply Clinical criteria: Patient must have received insufficient therapy with this drug under the Initial treatment (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at weeks 0, 2 and 6 weeks); OR Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; OR Patient must have received insufficient therapy with this drug to complete 24 weeks of treatment under the Initial PBS-subsidised treatment restriction for patients who had previously received non-PBS subsidised treatment (Grandfathered patient), AND The treatment must provide no more than the balance of up to 3 doses (new patients) or 2 repeats (Continuing patients or Grandfathered patients). Population criteria: Patient must be 6 years of age or older. Treatment criteria: Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR Must be treated by a paediatrician or specialist paediatric gastroenterologist if aged between 6 to 17 years. Note Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written applications for authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	

HOBART TAS 7001

Note

Special Pricing Arrangements apply.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug for this condition,

AND

Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR

Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years.

Treatment criteria:

Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a paediatrician or specialist paediatric gastroenterologist if aged between 6 to 17 years.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a PUCAI score less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Note

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

Special Pricing Arrangements apply.

10196P	infliximab 100 mg injection, 1 x 100 mg vial	1	..	..	751.70	Remicade	JC

INFLIXIMAB**Authority required**

Active ankylosing spondylitis

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis,

AND

Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab or infliximab in this treatment cycle,

AND

Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	

normal values for age and gender,

AND

Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) a signed patient acknowledgment.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 18 weeks of treatment with this drug will be approved under this criterion.

At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

Note

Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

Note

For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

Authority required

Ankylosing spondylitis

Treatment Phase: Initial 2 (change or recommencement for all patients)

Clinical criteria:

Patient must have a documented history of active ankylosing spondylitis,

AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle,

AND

Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle,

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

AND

Patient must be eligible to receive further bDMARD therapy.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 18 weeks of treatment with this drug will be approved under this criterion.

At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.

Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

Clinical criteria:

Patient must have active, or a documented history of active, ankylosing spondylitis,

AND

Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 18 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 18 weeks treatment,

AND

The treatment must provide no more than the balance of up to 18 weeks treatment available under the above restrictions.

Population criteria:

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
	Patient must be an adult.						
	Treatment criteria:						
	Must be treated by a rheumatologist.						
	Note						
	Authority approval for sufficient therapy to complete a maximum of 18 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).						
	Written application for authority approval for sufficient therapy to complete a maximum of 18 weeks of treatment should be forwarded to:						
	Department of Human Services						
	Prior Written Approval of Complex Drugs						
	Reply Paid 9826						
	GPO Box 9826						
	HOBART TAS 7001						
	Authority required						
	Ankylosing spondylitis						
	Treatment Phase: Continuing treatment						
	Clinical criteria:						
	Patient must have a documented history of active ankylosing spondylitis,						
	AND						
	Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,						
	AND						
	Patient must have demonstrated an adequate response to treatment with this drug.						
	Population criteria:						
	Patient must be an adult.						
	Treatment criteria:						
	Must be treated by a rheumatologist.						
	An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:						
	(a) an ESR measurement no greater than 25 mm per hour; or						
	(b) a CRP measurement no greater than 10 mg per L; or						
	(c) an ESR or CRP measurement reduced by at least 20% from baseline.						
	Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.						
	The authority application must be made in writing and must include:						
	(a) a completed authority prescription form; and						
	(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.						
	All measurements provided must be no more than 1 month old at the time of application.						
	A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.						
	At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.						
	All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.						
	Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.						
	Note						
	Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).						
	Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au						
	Applications for authority to prescribe should be forwarded to:						
	Department of Human Services						
	Prior Written Approval of Complex Drugs						

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.

Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty \$		
	The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements. For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. (4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured. <u>Authority required</u> Ankylosing spondylitis Treatment Phase: Continuing treatment – balance of supply Clinical criteria: Patient must have a documented history of active ankylosing spondylitis, AND Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Population criteria: Patient must be an adult. Treatment criteria: Must be treated by a rheumatologist. <u>Note</u> Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001						
5753T	infliximab 100 mg injection, 1 x 100 mg vial	1	..	..	751.70		Remicade JC

INFLIXIMAB

Authority required

Initial 1 (new patients)

Initial treatment of Crohn disease in a patient assessed by CDAI.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and

(b) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(c) has failed to achieve an adequate response to prior systemic therapy including:

(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and

(ii) immunosuppressive therapy including:

— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or

— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or

— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au). The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application: (a) have a severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as assessed. All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment. The most recent CDAI assessment must be no more than 1 month old at the time of application. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following: (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition; and (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and (iii) the signed patient acknowledgement. A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. A CDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment					
	<u>Authority required</u> Initial 2 Change or re-commencement of treatment of Crohn disease in a patient assessed by CDAI. Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who: (a) has a documented history of severe refractory Crohn disease; and (b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and (c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle. NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)]. To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction. Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist. Authority applications must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following: (i) the completed current Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; and (ii) details of prior TNF alfa antagonist treatment including details of date and duration of treatment. A maximum quantity and number of repeats to provide for an initial course of infliximb consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					Price for Max.	Qty	
					\$	\$	

infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

Authority required

Continuing treatment of Crohn disease in a patient assessed by CDAI.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

- (a) has a documented history of severe refractory Crohn disease; and
- (b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition.

The CDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, a CDAI assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

Authority required

Initial 1

Initial treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist, or consultant physician as specified in the NOTE below of a patient who satisfies the following criteria:

(a) has confirmed Crohn disease defined by standard clinical, endoscopic and/or imaging features, including histological evidence with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and

(b) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy; and

(c) has evidence of intestinal inflammation; and

(d) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(e) has failed to achieve an adequate response to prior systemic drug therapy including:

(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and

(ii) immunosuppressive therapy including:

— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or

— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or

— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) have evidence of intestinal inflammation, including:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR

(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;

AND/OR

(b) be assessed clinically as being in a high faecal output state;

AND/OR

(c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of infliximab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(ii) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iii) date of the most recent clinical assessment; and

(iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

Authority required

Initial 2

Change or re-commencement of treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient or a patient with extensive small intestine disease.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:

(a) has a documented history of severe refractory Crohn disease; and

(b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and

(c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist. Authority applications must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following: (i) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criteria, if relevant; and (ii). details of prior TNF alfa antagonist treatment including details of date and duration of treatment. A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment <u>Authority required</u> Continuing treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient. Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who: (a) has a documented history of severe refractory Crohn disease with intestinal inflammation and with short gut syndrome or with an ileostomy or colostomy; and (b) has demonstrated or sustained an adequate response to treatment with infliximab. NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)]. An adequate response to infliximab treatment is defined as: (a) improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR (ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN). Applications for authorisation must be made in writing and must include: (a) a completed authority prescription; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following: (i) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy or the date of clinical assessment. The patient's assessment must be no more than 1 month old at the time of application. If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated. The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion. Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab. Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient,					

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	to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.					
	Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)					
	Authority required					
	Initial 1					
	Initial treatment of Crohn disease in a patient with extensive small intestine disease.					
	Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:					
	(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and					
	(b) has extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; and					
	(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and					
	(d) has failed to achieve an adequate response to prior systemic therapy including:					
	(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and					
	(ii) immunosuppressive therapy including:					
	— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or					
	— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or					
	— methotrexate at a dose of at least 15 mg weekly for 3 or more months.					
	NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].					
	If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.					
	If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).					
	The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:					
	(a) have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220;					
	AND/OR					
	(b) have evidence of active intestinal inflammation, including:					
	(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR					
	(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR					
	(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;					
	AND/OR					
	(c) be assessed clinically as being in a high faecal output state;					
	AND/OR					
	(d) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of infliximab.					
	All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.					
	Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.					
	Applications for authorisation must be made in writing and must include:					
	(a) a completed authority prescription form; and					
	(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:					
	(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and					
	(ii) (1) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; or					
	(2) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the dates of assessment of the patient's condition, if relevant; and					
	(iii) date of the most recent clinical assessment; and					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					\$	\$	

(iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

Authority required

Continuing treatment of Crohn disease in a patient with extensive small intestine disease.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, or consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of severe refractory Crohn disease with extensive intestinal inflammation affecting more than 50 cm of the small intestine; and

(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:

(a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or

(b) improvement of intestinal inflammation as demonstrated by:

(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR

(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR

(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or

(c) reversal of high faecal output state; or

(d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy; or

(iii) the date of clinical assessment.

All assessments must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

Authority required

Initial 3 (grandfather)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	Initial PBS-subsidised treatment of Crohn disease in a patient assessed by CDAI who has previously received non-PBS-subsidised therapy with infliximab.					
	Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who:					
	(a) has a documented history of severe refractory Crohn disease and was receiving treatment with infliximab prior to 7 March 2007; and					
	(b) had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with infliximab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and					
	(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and					
	(d) has demonstrated or sustained an adequate response to treatment with infliximab. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).					
	NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].					
	An adequate response to infliximab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150.					
	Applications for authorisation must be made in writing and must include:					
	(a) a completed authority prescription form; and					
	(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:					
	(i) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; and					
	(ii) the signed patient acknowledgement.					
	The current CDAI assessment must be no more than 1 month old at the time of application. The baseline CDAI assessment must be from immediately prior to commencing treatment with infliximab.					
	The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.					
	Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.					
	Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.					
	At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.					
	Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).					
	Patients may qualify for PBS-subsidised treatment under this restriction once only					
	Authority required					
	Initial 3					
	Initial PBS-subsidised treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient, or a patient with extensive small intestine disease, who has previously received non-PBS-subsidised therapy with infliximab.					
	Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist, of a patient who:					
	(a) has a documented history of severe refractory Crohn disease and was receiving treatment with infliximab prior to 7 March 2007; and					
	(b) (1) has a history of extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; or					
	(2) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy with a documented history of intestinal inflammation; and					
	(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and					
	(d) has demonstrated or sustained an adequate response to treatment with infliximab according to the criteria included in the relevant continuation restriction. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).					
	NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].					
	The same criteria used to determine an inadequate response to prior treatment at baseline must be used to determine response to treatment and eligibility for continuing therapy, according to the criteria included in the continuing treatment restriction.					
	An adequate response to infliximab treatment is defined as:					
	(a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or					
	(b) improvement of intestinal inflammation as demonstrated by:					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR

(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR

(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or

(c) reversal of high faecal output state; or

(d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) (1) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet, where relevant, including the date of the assessment of the patient's condition; or

(2) the reports and dates of the current and baseline pathology or diagnostic imaging test(s) in order to assess response to therapy; or

(3) the date of clinical assessment(s); and

(ii) the signed patient acknowledgement.

The patient's assessment must be no more than 1 month old at the time of application. The baseline CDAI assessments must be from immediately prior to commencing treatment with infliximab. Where a baseline assessment is not available, please call Medicare Australia on 1800 700 270 to discuss.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

Note

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for adult patients with severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alpha antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alpha antagonists at any 1 time.

From 1 August 2008, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alpha antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alpha antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alpha antagonist treatment prior to 1 August 2008 is considered to be in their first cycle as of 1 August 2008.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alpha antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alpha antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alpha antagonist treatment in the most recent cycle to the date of the

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					\$	\$	

first application for initial treatment with a TNF- α antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF- α antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF- α antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF- α antagonist therapy after 1 August 2008.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF- α antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF- α antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF- α antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF- α antagonist.

For second and subsequent courses of PBS-subsidised TNF- α antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF- α antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF- α antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF- α antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF- α antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF- α antagonist is approved, a patient may swap if eligible to the alternate TNF- α antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, evidence of intestinal inflammation), or the prior corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate TNF- α antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF- α antagonist at the time of the application. However, they cannot swap to a particular TNF- α antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF- α antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF- α antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a TNF- α antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF- α antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.	Brand Name and Manufacturer	
					Qty \$		
	the CDAI score or the indices of intestinal inflammation are measured.						
	(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.						
	A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 9 November 2007 or infliximab prior to 7 March 2007 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.						
	A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.						
	Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.						
	'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.						
5754W	infliximab 100 mg injection, 1 x 100 mg vial	1	..	..	751.70	Remicade	JC

INFLIXIMAB

Authority required

Initial treatment of Crohn disease in a paediatric patient.

Initial PBS-subsidised treatment by a gastroenterologist, paediatrician or consultant physician as specified in the NOTE below, of a patient aged 6 to 17 years inclusive with moderate to severe refractory Crohn disease who satisfies the following criteria:

- (a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and
- (b) whose parent or authorised guardian has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
- (c) has failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including:
 - (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period;
 - (ii) an 8 week course of enteral nutrition;
 - (iii) immunosuppressive therapy including:
 - azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
 - 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
 - methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

- (a) severity of disease activity which results in a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
- (b) The most recent PCDAI assessment must be no more than 1 month old at the time of application.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition; and
 - (ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy], or dates of enteral nutrition; and
 - (iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty	\$	

infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

Authority required

Continuing treatment of Crohn disease in a patient initiated on PBS-subsidised treatment as a paediatric patient.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, paediatrician, consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

- (a) has a documented history of moderate to severe refractory Crohn disease; and
- (b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Paediatric Crohn Disease Activity Index (PCDAI) Score by at least 15 points as compared to baseline AND a total PCDAI score of 30 points or less.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.

The PCDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, a PCDAI assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

Patients who fail to demonstrate or sustain a response to treatment with infliximab for Crohn disease as specified in the criteria for continuing treatment with infliximab, will not be eligible to receive PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

Authority required

Initial PBS-subsidised treatment of Crohn disease in a paediatric patient who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, paediatrician, consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient aged 6 to 17 years inclusive who:

- (a) has a documented history of moderate to severe refractory Crohn disease and was receiving treatment with infliximab prior to 4 July 2007; and
- (b) had a Paediatric Crohn Disease Activity Index (PCDAI) Score of greater than 30 prior to commencing treatment with infliximab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and
- (c) whose parent or authorised guardian has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
- (d) has demonstrated or sustained an adequate response to treatment with infliximab. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Paediatric Crohn Disease Activity Index (PCDAI) Score by at least 15 points as compared to baseline AND a total PCDAI score of 30 points or less.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	
	Applications for authorisation must be made in writing and must include:					
	(a) a completed authority prescription form; and					
	(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:					
	(i) the completed current and baseline Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition; and					
	(ii) the signed patient acknowledgement.					
	The current PCDAI assessment must be no more than 1 month old at the time of application. The baseline PCDAI assessment must be from immediately prior to commencing treatment with infliximab.					
	The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.					
	Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.					
	Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.					
	Patients who fail to demonstrate or sustain a response to treatment with infliximab for Crohn disease as specified in the criteria for continuing treatment with infliximab, will not be eligible to recommence PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.					
	At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.					
	Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).					
	Patients may qualify for PBS-subsidised treatment under this restriction once only					
	Note					
	Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).					
	Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.					
	Written applications for authority to prescribe infliximab should be forwarded to:					
	Medicare Australia					
	Prior Written Approval of Specialised Drugs					
	Reply Paid 9826					
	GPO Box 9826					
	HOBART TAS 7001					
5755X	infliximab 100 mg injection, 1 x 100 mg vial	1	..	..	751.70	Remicade
						JC

INFLIXIMAB

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe active psoriatic arthritis,

AND

Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition,

AND

Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months,

AND

Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR

Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months,

AND

Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	Patient must be an adult. Treatment criteria: Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab. Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and either (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and (3) a signed patient acknowledgement. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised. Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au) Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment. Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle. Authority required Severe psoriatic arthritis Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment) Clinical criteria: Patient must have a documented history of severe active psoriatic arthritis, AND Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, AND Patient must not receive more than 22 weeks of treatment under this restriction. Population criteria: Patient must be an adult. Treatment criteria: Must be treated by a rheumatologist; OR					

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.					
	For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.					
	The authority application must be made in writing and must include:					
	(1) a completed authority prescription form; and					
	(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.					
	At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.					
	Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.					
	Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.					
	Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.					
	Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.					
	An adequate response to treatment is defined as:					
	an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and					
	either of the following:					
	(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or					
	(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:					
	(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or					
	(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).					
	Note					
	The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.					
	Note					
	Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.					
	Note					
	Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).					
	Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au					
	Applications for authority to prescribe should be forwarded to:					
	Department of Human Services					
	Prior Written Approval of Complex Drugs					
	Reply Paid 9826					
	GPO Box 9826					
	HOBART TAS 7001					
	Note					
	TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS					
	The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.					
	Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.					
	Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.					
	Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.					
	Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.					

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below]. The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle. Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment. Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle. Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime. How to prescribe biological agents for the treatment of severe active psoriatic arthritis. (1) Initial treatment. Applications for initial treatment should be made where: (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and (iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2). All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply. Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent. Grandfather patients - certolizumab pegol only. For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent. Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction. (2) Continuing treatment. Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent. (3) Swapping therapy. Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not. Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing: (i) they have not received PBS-subsidised treatment with that particular biological agent previously; or (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle. To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing. (4) Baseline measurements to determine response.					

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints. (5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured. <u>Authority required</u> Severe psoriatic arthritis Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply Clinical criteria: Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 22 weeks treatment, AND The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions. Treatment criteria: Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. <u>Note</u> Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written application for authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 <u>Authority required</u> Severe psoriatic arthritis Treatment Phase: Continuing treatment Clinical criteria: Patient must have a documented history of severe active psoriatic arthritis, AND Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, AND Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Population criteria: Patient must be an adult. Treatment criteria: Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

Note

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.					
	Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.					
	There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.					
	How to prescribe biological agents for the treatment of severe active psoriatic arthritis.					
	(1) Initial treatment.					
	Applications for initial treatment should be made where:					
	(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and					
	(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and					
	(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).					
	All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.					
	Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.					
	Grandfather patients - certolizumab pegol only.					
	For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.					
	Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.					
	(2) Continuing treatment.					
	Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.					
	Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.					
	Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.					
	(3) Swapping therapy.					
	Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.					
	Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.					
	Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:					
	(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or					
	(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialed it on the PBS; and					
	(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.					
	To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.					
	To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.					
	(4) Baseline measurements to determine response.					
	The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.					
	To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
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	(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.					
	Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.					
	<u>Authority required</u>					
	Severe psoriatic arthritis					
	Treatment Phase: Continuing treatment - balance of supply					
	Clinical criteria:					
	Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment,					
	AND					
	The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.					
	Treatment criteria:					
	Must be treated by a rheumatologist; OR					
	Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.					
	<u>Note</u>					
	Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).					
	Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:					
	Department of Human Services					
	Prior Written Approval of Complex Drugs					
	Reply Paid 9826					
	GPO Box 9826					
	HOBART TAS 7001					
5756Y	infliximab 100 mg injection, 1 x 100 mg vial	1	..	..	751.70	Remicade
						JC

INFLIXIMAB

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have severe active rheumatoid arthritis,

AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months,

AND

Patient must have not failed previous PBS-subsidised treatment with infliximab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times,

AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly,

AND

Patient must not receive more than 22 weeks of treatment under this restriction,

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					Price for Max.	Qty	
					\$	\$	

AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application including severity.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats will be authorised.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

Applications for a patient who has received PBS-subsidised treatment with infliximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with infliximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

- (a) a total active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list of major joints:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note

Special Pricing Arrangements apply.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.					
	A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.					
	Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.					
	Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.					
	For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.					
	Abatacept patients:					
	Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.					
	Rituximab patients:					
	A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.					
	(b) Continuing treatment.					
	Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.					
	It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.					
	Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.					
	Rituximab patients:					
	A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.					
	Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.					
	(2) Swapping therapy.					
	Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.					
	Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.					
	A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.					
	Abatacept patients:					
	Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.					
	In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.					
	To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.					
	PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.					
	To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.					
	(3) Baseline measurements to determine response.					
	The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline					

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	measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.					
	To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.					
	Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.					
	Authority required					
	Severe active rheumatoid arthritis					
	Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).					
	Clinical criteria:					
	Patient must have a documented history of severe active rheumatoid arthritis,					
	AND					
	Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy,					
	AND					
	Patient must not receive more than 22 weeks of treatment under this restriction,					
	AND					
	The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.					
	Population criteria:					
	Patient must be aged 18 years or older.					
	Treatment criteria:					
	Must be treated by a rheumatologist; OR					
	Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.					
	For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.					
	The authority application must be made in writing and must include:					
	(a) a completed authority prescription form; and					
	(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.					
	At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats will be authorised.					
	Applications for a patient who has received PBS-subsidised treatment with infliximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below.					
	Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.					
	Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.					
	Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.					
	If a patient fails to demonstrate a response to a treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.					
	A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.					
	An adequate response to treatment is defined as:					
	an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;					
	AND either of the following:					
	(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or					
	(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:					
	(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or					
	(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement. where pain and limitation of movement are					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty	\$	

due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alpha antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	
	Abatacept patients: Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application. Rituximab patients: A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate. (b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients: A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. (2) Swapping therapy. Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled. Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent. A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug. Abatacept patients: Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation. In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment. To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period. To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing. (3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.					

Authority required

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	Severe active rheumatoid arthritis					
	Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.					
	Clinical criteria:					
	Patient must have received insufficient infliximab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 22 weeks treatment; OR					
	Patient must have received insufficient infliximab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 22 weeks treatment,					
	AND					
	The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.					
	Treatment criteria:					
	Must be treated by a rheumatologist; OR					
	Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.					
	Note					
	Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).					
	Written application for authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment should be forwarded to:					
	Department of Human Services					
	Prior Written Approval of Complex Drugs					
	Reply Paid 9826					
	HOBART TAS 7001					
	Authority required					
	Severe active rheumatoid arthritis					
	Treatment Phase: Continuing treatment.					
	Clinical criteria:					
	Patient must have a documented history of severe active rheumatoid arthritis,					
	AND					
	Patient must have demonstrated an adequate response to treatment with infliximab,					
	AND					
	Patient must have received infliximab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment,					
	AND					
	Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction,					
	AND					
	The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.					
	Population criteria:					
	Patient must be aged 18 years or older.					
	Treatment criteria:					
	Must be treated by a rheumatologist; OR					
	Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.					
	For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.					
	An adequate response to treatment is defined as:					
	an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;					
	AND either of the following:					
	(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or					
	(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:					
	(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or					
	(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).					
	Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for single infusion at a dose of 3 mg per kg. Up to a maximum of 2 repeats will be authorised.

All applications for continuing treatment with infliximab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

If a patient fails to demonstrate a response to treatment with infliximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

- (1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

- (a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with

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	that agent (Initial 2).					
	Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.					
	Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.					
	A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.					
	Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.					
	Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.					
	For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.					
	Abatacept patients:					
	Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.					
	Rituximab patients:					
	A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.					
	(b) Continuing treatment.					
	Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.					
	It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.					
	Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.					
	Rituximab patients:					
	A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.					
	Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.					
	(2) Swapping therapy.					
	Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.					
	Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.					
	A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.					
	Abatacept patients:					
	Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.					
	In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.					
	To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.					
	PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.					
	To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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	(3) Baseline measurements to determine response.					
	The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. <u>Authority required</u> Severe active rheumatoid arthritis Treatment Phase: Continuing Treatment – balance of supply. Clinical criteria: Patient must have received insufficient infliximab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Treatment criteria: Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. <u>Note</u> Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001					
5757B	infliximab 100 mg injection, 1 x 100 mg vial	1	..	..	751.70	Remicade JC

INFLIXIMAB

Authority required

Initial treatment [Initial 1, Whole body (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

- (a) have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and
- (b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
- (c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); and
- (d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:
 - (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or
 - (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or
 - (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or
 - (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]]; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

Authority required

Initial or re-Treatment [Initial 2, Whole body (Received prior biological agent under PBS)]

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised therapy with infliximab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]]; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised infliximab treatment within this Treatment Cycle and who wish to re-commence infliximab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised infliximab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

Authority required

Continuing treatment (Whole body)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

- (a) who have a documented history of severe chronic plaque psoriasis; and
- (b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with infliximab; and
- (c) who have demonstrated an adequate response to their most recent course of treatment with infliximab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-biological treatment baseline value for this Treatment Cycle.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet along with the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with infliximab.

A maximum of 24 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

Authority required

Initial treatment [Initial 1, Face, hand, foot (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

- (a) have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and
- (b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
- (c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot); and
- (d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:
 - (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or
 - (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or
 - (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or
 - (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

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	If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au). The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application: (a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment. (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment. (c) The most recent PASI assessment must be no more than 1 month old at the time of application. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following: (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] and (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and (iii) the signed patient and prescriber acknowledgements. A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised. Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks. A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss. It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline					
	Authority required Initial or re-Treatment [Initial 2, Face, hand, foot (Received prior biological agent under PBS)] Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who: (a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and (b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and (c) have not failed PBS-subsidised therapy with infliximab for the treatment of this condition in the current Treatment Cycle. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following: (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] and (ii) details of prior biological treatment, including dosage, date and duration of treatment. Applications for patients who have demonstrated a response to PBS-subsidised infliximab treatment within this Treatment Cycle and who wish to re-commence infliximab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised infliximab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment. A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient,					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
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					\$	\$	

to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority required

Continuing treatment (Face, hand, foot)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

- (a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and
- (b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with infliximab; and
- (c) who have demonstrated an adequate response to treatment with infliximab.

An adequate response to infliximab treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

The most recent PASI assessment must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab and ustekinumab.

From 1 March 2010, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept, infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 March 2010 is considered to be in their first Cycle as of 1 March 2010.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 March 2010, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2010.

Patients must be assessed for response to each course of continuing treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 March 2010.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or
- (iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept, infliximab or ustekinumab it is recommended that a

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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	patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.					
	Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.					
	(4) Swapping therapy.					
	Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.					
	Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.					
	Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.					
	Patients who commenced treatment with adalimumab prior to 1 June 2009 or ustekinumab prior to 1 March 2010 access these interchangeability arrangements in the same way as patients who have not.					
	To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.					
	To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.					
	(5) Baseline measurements to determine response.					
	Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.					
	To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.					
	(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.					
	Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.					
	Note					
	No applications for increased repeats will be authorised.					
5758C	infliximab 100 mg injection, 1 x 100 mg vial	1	..	..	751.70	Remicade
						JC

INFLIXIMAB

Authority required

Initial 1

Initial treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and

(b) has an externally draining enterocutaneous or rectovaginal fistula; and

(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and

(ii) a signed patient acknowledgement.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6 will be authorised.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					\$	\$	

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

Authority required

Initial 2

Change or re-commencement of treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with infliximab of complex refractory fistulising Crohn disease by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

- (a) has a documented history of complex refractory fistulising Crohn disease; and
- (b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or infliximab for a draining enterocutaneous or rectovaginal fistula; and
- (c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and
 - (ii) details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

Authority required

Initial 3 (grandfather)

Initial PBS-subsidised treatment of complex refractory FISTULISING CROHN DISEASE in a patient who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who satisfies the following criteria:

- (a) has a documented history of complex refractory fistulising Crohn disease and was receiving treatment with infliximab prior to 1 March 2010; and
- (b) had a draining enterocutaneous or rectovaginal fistula(e) prior to commencing treatment with infliximab; and
- (c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and (d) is receiving treatment with infliximab at the time of application; and (e) has demonstrated or sustained an adequate response to treatment with infliximab. NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)]. An adequate response to infliximab treatment is defined as: (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient. Applications for authorisation must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following: (i) a completed current and baseline Fistula Assessment form including the date of assessment of the patient's condition; and (ii) a signed patient acknowledgement. The current fistula assessment must be no more than 1 month old at the time of application. The baseline fistula assessment must be from immediately prior to commencing treatment with infliximab. An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria. Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab. Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised. Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Patients may qualify for PBS-subsidised treatment under this restriction once only					
	Authority required Continuing treatment of complex refractory FISTULISING CROHN DISEASE. Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who: (a) has a documented history of complex refractory fistulising Crohn disease; and (b) has demonstrated or sustained an adequate response to treatment with infliximab. NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)]. An adequate response is defined as: (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient. Authority applications must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition. The fistula assessment must be no more than 1 month old at the time of application. If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated. An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria. Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab. Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

Note

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term 'tumour necrosis factor (TNF) alpha antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 April 2011 is considered to be in their first cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
	(b) Continuing treatment.						
	Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply. Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.						
	(2) Swapping therapy.						
	Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle. A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.						
	(3) Baseline measurements to determine response.						
	Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.						
	(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.						
	A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.						
	(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.						
	A patient who commenced treatment with adalimumab for complex refractory fistulising Crohn disease prior to 4 November 2010 or infliximab prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.						
9654D	infliximab 100 mg injection, 1 x 100 mg vial	1	..	..	751.70		Remicade JC

Interleukin inhibitors

TOCILIZUMAB

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

Clinical criteria:

Patient must have severe active juvenile idiopathic arthritis,

AND

Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition;
OR

Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months,

AND

Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR

Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months,

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty	\$	

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and

(3) an acknowledgement signed by a parent or authorised guardian.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

Note

Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					Qty	\$	

supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis,

AND

Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle,

AND

Patient must not have failed PBS-subsidised therapy with tocilizumab for this condition in the current treatment cycle,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be under 18 years of age.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					\$	\$	

Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	

Clinical criteria:

Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment,

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis,

AND

Patient must have demonstrated an adequate response to treatment with tocilizumab,

AND

Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					Qty	\$	

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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Applications for authority to prescribe should be forwarded to:

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Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					Price for Max. Qty \$	

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing Treatment – balance of supply

Clinical criteria:

Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment,

AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					Price for Max. Qty \$		
Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.							
Note							
Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).							
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:							
Department of Human Services							
Prior Written Approval of Complex Drugs							
Reply Paid 9826							
GPO Box 9826							
HOBART TAS 7001							
10056G	tocilizumab 200 mg/10 mL injection, 1 x 10 mL vial	1	..	..	467.20	Actemra	RO
10064Q	tocilizumab 400 mg/20 mL injection, 1 x 20 mL vial	1	..	..	934.40	Actemra	RO
10077J	tocilizumab 80 mg/4 mL injection, 1 x 4 mL vial	1	..	..	186.88	Actemra	RO

TOCILIZUMAB

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years,

AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months; OR

Patient must have received no PBS-subsidised bDMARD treatment for at least 5 years if they failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) in their last treatment cycle,

AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					\$	\$	

intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle.

Note

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;

(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;

(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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	Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au					
	Applications for authority to prescribe should be forwarded to:					
	Department of Human Services					
	Prior Written Approval of Complex Drugs					
	Reply Paid 9826					
	GPO Box 9826					
	HOBART TAS 7001					
	Note					
	TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS					
	The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.					
	A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.					
	From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:					
	(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and					
	(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.					
	Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.					
	A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.					
	A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.					
	A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.					
	There is no limit to the number of treatment cycles a patient may undertake.					
	(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.					
	(a) Initial treatment.					
	Applications for initial treatment should be made where:					
	(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or					
	(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or					
	(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or					
	(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).					
	Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.					
	A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.					
	Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.					
	For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.					
	(b) Continuing treatment.					
	Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.					
	A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.					
	It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.					
	Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	

the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 24 months)

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years,

AND

Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle,

AND

Patient must not have failed PBS-subsidised therapy with tocilizumab for this condition in the current treatment cycle,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					\$	\$	

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply

Clinical criteria:

Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment,

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					Price for Max.	Qty	
					\$	\$	

Note

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years,

AND

Patient must have demonstrated an adequate response to treatment with tocilizumab,

AND

Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					Price for Max.	Qty	
					\$	\$	

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

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Note

TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max. Qty \$		
	A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course. (b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. (2) Swapping therapy. Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing. (3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement. (4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy. A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction. <u>Authority required</u> Severe active juvenile idiopathic arthritis Treatment Phase: Continuing Treatment – balance of supply Clinical criteria: Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Treatment criteria: Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. <u>Note</u> Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001						
10058J	tocilizumab 200 mg/10 mL injection, 1 x 10 mL vial	1	..	..	467.20		Actemra
							RO

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer	
10072D	tocilizumab 400 mg/20 mL injection, 1 x 20 mL vial	1	..	..	934.40	Actemra	RO
10081N	tocilizumab 80 mg/4 mL injection, 1 x 4 mL vial	1	..	..	186.88	Actemra	RO

TOCILIZUMAB

Authority required

Initial 1 (new and recommencing patients after a break of more than 12 months)

Initial treatment by a rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient under 18 years who:

(a) has been diagnosed with systemic juvenile idiopathic arthritis; AND

(b) has polyarticular course disease and either:

(i) failure to achieve an adequate response to the following treatment regimen (see (1) below for definition of failure to achieve an adequate response):

— oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids for a minimum of 3 months; or

(ii) severe intolerance of, or toxicity due to, methotrexate (see (2) below for definition of severe intolerance and toxicity); OR

(c) has refractory systemic symptoms, demonstrated by:

— an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy; AND

(d) has not received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months.

(1) The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy and must be demonstrated in all patients at the time of the initial application:

(a) in a patient with polyarticular course disease:

(i) an active joint count of at least 20 active (swollen and tender) joints; OR

(ii) at least 4 active joints from the following list:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); AND/OR

— shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) an active joint count of at least 2 active joints; AND

(ii) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; AND/OR

(iii) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

(2) Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant NSAIDs on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonia, or serious sepsis.

If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, please provide details at time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of this toxicity at the time of application.

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be provided for all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the date of assessment of severe active systemic juvenile idiopathic arthritis;

(ii) details of prior treatment including dose and duration of treatment;

(iii) pathology reports detailing CRP and platelet count where appropriate; and

(3) a signed patient or authorised guardian acknowledgement form.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

A maximum of 16 weeks of treatment will be authorised under this restriction.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					\$	\$	

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 4 weeks from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to 2 courses of treatment in a treatment cycle they will not be eligible to receive further PBS-subsidised tocilizumab therapy in that treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle

Authority required

Initial 2 (retrial or recommencement of treatment after a break of less than 12 months)

Initial PBS-subsidised treatment by a rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient who:

- (a) has a documented history of systemic juvenile idiopathic arthritis; AND
- (b) has received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months; AND
- (c) has not failed PBS-subsidised therapy with tocilizumab for this condition more than once in the current treatment cycle.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) pathology reports detailing CRP and platelet count where appropriate.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with tocilizumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria. Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with tocilizumab.

Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to that course of tocilizumab.

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle

Authority required

Initial 3 ('grandfather' patients)

Initial treatment by a rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient who:

- (a) has a documented history of systemic juvenile idiopathic arthritis; and
- (b) was receiving treatment with tocilizumab prior 1 November 2011; and
- (c) has demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with tocilizumab; and
- (d) is receiving treatment with tocilizumab at the time of application.

To ensure consistency in determining response, the same indices of disease severity used to establish the baseline must be provided for all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) pathology reports detailing CRP and platelet count where appropriate; and

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					\$	\$	

(3) a signed patient or authorised guardian acknowledgement form.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

The baseline systemic juvenile idiopathic arthritis assessment must be provided and must be from immediately prior to commencing treatment with tocilizumab. (See NOTE (3) above for definition of baseline measurements to determine response.)

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with tocilizumab.

Patients are eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one months supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

A patient may only qualify for PBS-subsidised treatment under this restriction once

Authority required

Continuing treatment

Continuing treatment with tocilizumab, by a rheumatologist or under the supervision of a paediatric rheumatology treatment centre, of a patient who:

- (a) has a documented history of systemic juvenile idiopathic arthritis; AND
- (b) has demonstrated an adequate response to treatment with tocilizumab.

An adequate response to treatment is defined as:

- (a) in a patient with polyarticular course disease:

- (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

- (b) in a patient with refractory systemic symptoms:

- (i) absence of fever greater than 38 degrees Celsius in the preceding seven days; AND/OR
- (ii) a reduction in the CRP level and platelet count by at least 30% from baseline; AND/OR
- (iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

- (i) baseline and current pathology reports detailing CRP and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the Initial treatment restriction, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients are eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of initial application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle

Note

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					\$	\$	

Any queries concerning the arrangements to prescribe tocilizumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Further prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe tocilizumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alpha antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					\$	\$	

month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

Note

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
	patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.						

Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tocilizumab for a patient who has severe active systemic juvenile idiopathic arthritis (sJIA).

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

- continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show a response to therapy, and
- fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

Once a patient has either failed or ceased to respond to 2 courses of treatment, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised tocilizumab therapy before they are eligible to receive further PBS-subsidised tocilizumab therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was stopped to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

A patient who was receiving PBS-subsidised tocilizumab treatment immediately prior to 1 May 2012 is considered to be in their first cycle as of 1 May 2012. A patient who has had a break in tocilizumab treatment of at least 12 months immediately prior to making a new application, on or after 1 May 2012, will commence a new treatment cycle.

A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of less than 12 months may commence a second course of treatment within the same treatment cycle.

A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

(1) How to prescribe PBS-subsidised tocilizumab therapy after 1 May 2012.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised tocilizumab treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with tocilizumab following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
- (iii) a patient has received the first course of PBS-subsidised (initial or continuing) tocilizumab therapy in a treatment cycle and is deemed to have failed to respond or sustain a response and the treating physician wishes to trial a second course (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab for that course.

For second and subsequent courses of PBS-subsidised tocilizumab, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with tocilizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with tocilizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted tocilizumab supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

(2) Treatment cycle.

Once initial treatment with PBS-subsidised tocilizumab is approved, a patient deemed to have failed to respond to the first course of treatment may have a second course without having to requalify with respect to the indices of disease severity (joint count, fever and/or CRP level and platelet count) or the prior therapy requirements, except if the patient has had a break in therapy of more than 12 months.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the relevant baseline measurements of the joint count, fever and/or CRP level and platelet count submitted with the first authority application for tocilizumab.

Where a patient is deemed to have failed to respond or to sustain a response to the first course of therapy in a treatment cycle, prescribers may provide new baseline measurements for the second course of treatment within that cycle. Medicare Australia will assess response according to these revised baseline measurements. If new baseline measurements are not submitted with the initial application for the second course of

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.	Brand Name and Manufacturer	
					Qty \$		
	treatment, then those submitted with the first course will be used by Medicare Australia to assess response to the second course.						
	(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.						
	A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised tocilizumab therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.						
	(5) Patients 'grandfathered' onto PBS-subsidised treatment with tocilizumab.						
	A patient who commenced treatment with tocilizumab for severe active systemic juvenile idiopathic arthritis prior to 1 November 2011 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.						
	A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with tocilizumab will be authorised under this criterion.						
	Following completion of the initial PBS-subsidised course, further applications for treatment with tocilizumab will be assessed under the continuing treatment restriction.						
	'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 12 month break in PBS-subsidised therapy' above for further details.						
	(6) Withdrawal of treatment after sustained remission.						
	Withdrawal of treatment with tocilizumab should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to Medicare Australia at the time treatment is ceased.						
	Note						
	Special Pricing Arrangements apply.						
1481Y	tocilizumab 200 mg/10 mL injection, 1 x 10 mL vial	1	..	..	467.20	Actemra	RO
1482B	tocilizumab 400 mg/20 mL injection, 1 x 20 mL vial	1	..	..	934.40	Actemra	RO
1476Q	tocilizumab 80 mg/4 mL injection, 1 x 4 mL vial	1	..	..	186.88	Actemra	RO

TOCILIZUMAB

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have severe active rheumatoid arthritis,

AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months,

AND

Patient must not have failed previous PBS-subsidised treatment with tocilizumab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times,

AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to demonstrate a response to treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

- (a) a total active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list of major joints:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note

Special Pricing Arrangements apply.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	

Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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	Rituximab patients:					
	A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.					
	(b) Continuing treatment.					
	Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.					
	It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.					
	Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.					
	Rituximab patients:					
	A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.					
	Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.					
	(2) Swapping therapy.					
	Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.					
	Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.					
	A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.					
	Abatacept patients:					
	Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.					
	In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.					
	To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.					
	PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.					
	To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.					
	(3) Baseline measurements to determine response.					
	the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.					
	To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.					
	Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.					

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis,

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					\$	\$	

AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

The authority application must be made in writing and must include:

- (a) completed authority prescription form(s); and
- (b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to demonstrate a response to a treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

Special Pricing Arrangements apply.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					\$	\$	

restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					\$	\$	

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

Clinical criteria:

Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment,

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					Qty	\$	

Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment.

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis,

AND

Patient must have demonstrated an adequate response to treatment with tocilizumab,

AND

Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to demonstrate a response to treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty	\$	

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alpha antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					Price for Max.	Qty	
					\$	\$	

prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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Clinical criteria:							
Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment,							
AND							
The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.							
Treatment criteria:							
Must be treated by a rheumatologist; OR							
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.							
Note							
Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).							
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:							
Department of Human Services							
Prior Written Approval of Complex Drugs							
Reply Paid 9826							
GPO Box 9826							
HOBART TAS 7001							
9658H	tocilizumab 200 mg/10 mL injection, 1 x 10 mL vial	1	..	..	467.20	Actemra	RO
9659J	tocilizumab 400 mg/20 mL injection, 1 x 20 mL vial	1	..	..	934.40	Actemra	RO
9657G	tocilizumab 80 mg/4 mL injection, 1 x 4 mL vial	1	..	..	186.88	Actemra	RO

Calcineurin inhibitors

CYCLOSPORIN

Authority required (STREAMLINED)

3328

Management of rejection in patients following organ or tissue transplantation, under the supervision and direction of a transplant unit. Management includes initiation, stabilisation and review of therapy as required

Authority required (STREAMLINED)

3329

Management (which includes initiation, stabilisation and review of therapy) by dermatologists or clinical immunologists of patients with severe atopic dermatitis for whom other systemic therapies are ineffective or inappropriate

Authority required (STREAMLINED)

3330

Management (which includes initiation, stabilisation and review of therapy) by dermatologists of patients with severe psoriasis for whom other systemic therapies are ineffective or inappropriate and in whom the disease has caused significant interference with quality of life

Authority required (STREAMLINED)

3331

Management (which includes initiation, stabilisation and review of therapy) by nephrologists of patients with nephrotic syndrome in patients in whom steroids and cytostatic drugs have failed or are not tolerated or are considered inappropriate and in whom renal function is unimpaired

Authority required (STREAMLINED)

3332

Management (which includes initiation, stabilisation and review of therapy) by rheumatologists or clinical immunologists of patients with severe active rheumatoid arthritis for whom classical slow-acting anti-rheumatic agents (including methotrexate) are ineffective or inappropriate

Caution

Careful monitoring of patients is mandatory.

5632K	cyclosporin 10 mg capsule, 60	2	5	..	*74.40		Neoral 10	NV
5636P	cyclosporin 100 mg capsule, 30	4	5	..	*651.08	^a	Cyclosporin Sandoz	SZ
						^a	Neoral 100	NV
5633L	cyclosporin 100 mg/mL oral liquid, 50 mL	4	5	..	*1263.16		Neoral	NV
5634M	cyclosporin 25 mg capsule, 30	4	5	..	*153.56	^a	Cyclosporin Sandoz	SZ
						^a	Neoral 25	NV
5635N	cyclosporin 50 mg capsule, 30	4	5	..	*319.52	^a	Cyclosporin Sandoz	SZ
						^a	Neoral 50	NV

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					Qty \$			
CYCLOSPORIN								
<u>Authority required (STREAMLINED)</u>								
3333								
For use by organ or tissue transplant recipients								
<u>Caution</u>								
Careful monitoring of patients is mandatory.								
5631J	cyclosporin 50 mg/mL injection, 10 x 1 mL ampoules	1	..	..	54.10		Sandimmun	NV
TACROLIMUS								
<u>Authority required (STREAMLINED)</u>								
3328								
Management of rejection in patients following organ or tissue transplantation, under the supervision and direction of a transplant unit.								
Management includes initiation, stabilisation and review of therapy as required								
<u>Caution</u>								
Careful monitoring of patients is mandatory.								
9560E	tacrolimus 1 mg capsule, 100	2	5	..	*587.56	^a	Pharmacor Tacrolimus 1	CR
						^a	Prograf	LL
						^a	Tacrolimus Sandoz	SZ
9665Q	tacrolimus 1 mg capsule: modified release, 60 capsules	2	5	..	*352.52		Prograf XL	LL
9561F	tacrolimus 5 mg capsule, 50	2	5	..	*1468.16	^a	Pharmacor Tacrolimus 5	CR
						^a	Prograf	LL
						^a	Tacrolimus Sandoz	SZ
9666R	tacrolimus 5 mg capsule: modified release, 30 capsules	2	5	..	*881.36		Prograf XL	LL
9558C	tacrolimus 500 microgram capsule, 100	2	5	..	*293.78	^a	Pharmacor Tacrolimus 0.5	CR
						^a	Prograf	LL
						^a	Tacrolimus Sandoz	SZ
9664P	tacrolimus 500 microgram capsule: modified release, 30 capsules	2	5	..	*88.14		Prograf XL	LL

Other immunosuppressants

LENALIDOMIDE

Authority required

Myelodysplastic syndrome

Treatment Phase: Initial treatment

Clinical criteria:

The treatment must be limited to a maximum duration of 16 weeks,

AND

Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS),

AND

Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities,

AND

Patient must be red blood cell transfusion dependent.

Classification of a patient as Low risk requires a score of 0 on the IPSS, achieved with the following combination: less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias.

Classification of a patient as Intermediate-1 requires a score of 0.5 to 1 on the IPSS, achieved with the following possible combinations:

1. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias; OR
2. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
3. less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
4. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 2/3 cytopenias; OR
5. 5%-10% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
6. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
7. less than 5% marrow blasts with poor karyotypic status (complex, greater than 3 abnormalities), and 0/1 cytopenias.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					Price for Max.	Qty	
					\$	\$	

Classification of a patient as red blood cell transfusion dependent requires that:

(i) the patient has been transfused within the last 8 weeks; and

(ii) the patient has received at least 8 units of red blood cell in the last 6 months prior to commencing PBS-subsidised therapy with lenalidomide; and would be expected to continue this requirement without lenalidomide treatment.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Myelodysplastic Syndrome Lenalidomide Authority Application - Supporting Information Form; and

(c) a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and

(d) a copy of the full blood examination report; and

(e) a copy of the pathology report detailing the cytogenetics demonstrating Low risk or Intermediate-1 disease according to the IPSS (note: using Fluorescence in Situ Hybridization (FISH) to demonstrate MDS -5q is acceptable); and

(f) details of transfusion requirements including: (i) the date of most recent transfusion and the number of red blood cell units transfused; and (ii) the total number of red cell units transfused in the 4 and 6 months preceding the date of this application; and

(g) a signed patient acknowledgement form.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

Special Pricing Arrangements apply.

Authority required

Myelodysplastic syndrome

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS),

AND

Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities,

AND

Patient must have received PBS-subsidised initial therapy with lenalidomide for myelodysplastic syndrome,

AND

Patient must have achieved and maintained transfusion independence; or least a 50% reduction in red blood cell unit transfusion requirements compared with the four month period prior to commencing initial PBS-subsidised therapy with lenalidomide,

AND

Patient must not have progressive disease.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

The first authority application for continuing supply must be made in writing. Subsequent authority applications for continuing supply may be made by telephone.

The following evidence of response must be provided at each application:

(i) a haemoglobin level taken within the last 4 weeks; and

(ii) the date of the last transfusion; and

(iii) a statement of the number of units of red cells transfused in the 4 months immediately preceding this application; and

(iv) a statement confirming that the patient has not progressed to acute myeloid leukaemia.

Note

Written applications for authority to prescribe should be forwarded to:

Department of Human Services

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer	
					Price for Max. Qty \$		
	Prior Written Approval of Complex Drugs						
	Reply Paid 9826						
	GPO Box 9826						
	HOBART TAS 7001						
	Note						
	Subsequent authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).						
	Note						
	Special Pricing Arrangements apply.						
2802L	lenalidomide 10 mg capsule, 21	1	3	..	5643.33	Revlimid	CJ
2799H	lenalidomide 5 mg capsule, 21	1	3	..	5392.38	Revlimid	CJ

LENALIDOMIDE

Authority required

Multiple myeloma

Treatment Phase: Initial PBS-subsidised treatment

Clinical criteria:

The condition must be confirmed by a histological diagnosis,

AND

The treatment must be as monotherapy; OR

The treatment must be in combination with dexamethasone,

AND

Patient must have progressive disease after at least one prior therapy,

AND

Patient must have undergone or be ineligible for a primary stem cell transplant,

AND

Patient must have experienced treatment failure after a trial of at least four (4) weeks of thalidomide at a dose of at least 100 mg daily or have failed to achieve at least a minimal response after eight (8) or more weeks of thalidomide-based therapy for progressive disease,

AND

Patient must not be receiving concomitant PBS-subsidised bortezomib.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Thalidomide treatment failure is defined as:

- (1) confirmed disease progression during thalidomide treatment or within 6 months of discontinuing thalidomide treatment; or
- (2) severe intolerance or toxicity unresponsive to clinically appropriate dose adjustment.

Severe intolerance due to thalidomide is defined as unacceptable somnolence or sedation interfering with activities of daily living.

Toxicity from thalidomide is defined as peripheral neuropathy (Grade 2 or greater, interfering with function), drug-related seizures, serious Grade 3 or 4 drug-related dermatological reactions, such as Stevens-Johnson Syndrome, or other Grade 3 or 4 toxicity.

Failure to achieve at least a minimal response after 8 or more weeks of thalidomide-based therapy for progressive disease is defined as:

- (1) less than a 25% reduction in serum or urine M protein; or
- (2) in oligo-secretory and non-secretory myeloma patients only, less than a 25% reduction in the difference between involved and uninvolved serum free light chain levels.

If the dosing requirement for thalidomide cannot be met, the application must state the reasons why this criterion cannot be satisfied.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; details of thalidomide treatment failure; details of the basis of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response; and
- (3) duration of thalidomide and daily dose prescribed; and
- (4) a signed patient acknowledgment.

To enable confirmation of eligibility for treatment, current diagnostic reports of at least one of the following must be provided:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

Special Pricing Arrangements apply.

Authority required

Multiple myeloma

Treatment Phase: Continuing PBS-subsidised treatment

Clinical criteria:

Patient must have previously received an authority prescription for lenalidomide,

AND

Patient must not have progressive disease,

AND

The treatment must be as monotherapy; OR

The treatment must be in combination with dexamethasone.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					Price for Max. Qty \$		
Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.							
<u>Note</u>							
Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).							
<u>Note</u>							
Written applications for authority to prescribe should be forwarded to:							
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Reply Paid 9826							
GPO Box 9826							
HOBART TAS 7001							
<u>Note</u>							
Special Pricing Arrangements apply.							
5784K	lenalidomide 10 mg capsule, 21	1	..	..	5643.33	Revlimid	CJ
5785L	lenalidomide 15 mg capsule, 21	1	..	..	6581.61	Revlimid	CJ
5786M	lenalidomide 25 mg capsule, 21	1	..	..	6934.20	Revlimid	CJ
5783J	lenalidomide 5 mg capsule, 21	1	..	..	5392.38	Revlimid	CJ

RITUXIMAB

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have severe active rheumatoid arthritis,

AND

Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist,

AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months,

AND

Patient must not have failed previous PBS-subsidised treatment with rituximab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times,

AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly,

AND

Patient must not receive more than 2 infusions of rituximab under this restriction,

AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	
	Patient must be aged 18 years or older.					
	Treatment criteria:					
	Must be treated by a rheumatologist; OR					
	Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.					
	For the purposes of this restriction 'TNF' alfa antagonist means adalimumab, certolizumab pegol, etanercept, golimumab and infliximab.					
	For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab					
	If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.					
	The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.					
	The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.					
	If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.					
	The authority application must be made in writing and must include:					
	(1) completed authority prescription form(s); and					
	(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and					
	(3) a signed patient acknowledgement.					
	Assessment of a patient's response to an initial course of treatment must be made at least 12 weeks after the first infusion so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services within 4 weeks of the date it was conducted. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.					
	A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.					
	If a patient who fails to demonstrate a response to treatment with rituximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.					
	A patient who fails to demonstrate a response to rituximab treatment and who qualifies to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.					
	The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:					
	an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either					
	(a) a total active joint count of at least 20 active (swollen and tender) joints; or					
	(b) at least 4 active joints from the following list of major joints:					
	(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or					
	(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).					
	The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.					
	If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.					
	Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response					
	<u>Note</u>					
	The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:					
	(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;					
	(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
	(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.						

Note

Special Pricing Arrangements apply.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alpha antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.					
	Abatacept patients:					
	Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.					
	Rituximab patients:					
	A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.					
	(b) Continuing treatment.					
	Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.					
	It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.					
	Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.					
	Rituximab patients:					
	A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.					
	Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.					
	(2) Swapping therapy.					
	Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.					
	Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.					
	A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.					
	Abatacept patients:					
	Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.					
	In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.					
	To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.					
	PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.					
	To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.					
	(3) Baseline measurements to determine response.					
	The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.					
	To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.					
	Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients					

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.					
	<u>Authority required</u>					
	Severe active rheumatoid arthritis					
	Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).					
	Clinical criteria:					
	Patient must have a documented history of severe active rheumatoid arthritis,					
	AND					
	Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist,					
	AND					
	Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy,					
	AND					
	Patient must not receive more than 2 infusions of rituximab under this restriction,					
	AND					
	The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.					
	Population criteria:					
	Patient must be aged 18 years or older.					
	Treatment criteria:					
	Must be treated by a rheumatologist; OR					
	Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.					
	For the purposes of this restriction 'TNF' alfa antagonist means adalimumab, certolizumab pegol, etanercept, golimumab and infliximab.					
	For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab					
	The authority application must be made in writing and must include:					
	(a) completed authority prescription form(s); and					
	(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.					
	Applications for a patient who has received PBS-subsidised treatment with rituximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised rituximab treatment, within the timeframes specified below.					
	Where the most recent course of PBS-subsidised rituximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response at least 12 weeks after the first infusion. This assessment must be submitted no later than 4 weeks from the date of the assessment.					
	A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted within 4 weeks of assessment.					
	Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.					
	A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.					
	If a patient fails to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.					
	If a patient fails to demonstrate a response to a treatment with rituximab and who qualify to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.					
	An adequate response to treatment is defined as:					
	an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;					
	AND either of the following:					
	(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or					
	(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:					
	(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or					
	(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).					
	<u>Note</u>					
	Special Pricing Arrangements apply.					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

Note

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Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application. Rituximab patients: A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate. (b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients: A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. (2) Swapping therapy. Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled. Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent. A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug. Abatacept patients: Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation. In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment. To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period. To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing. (3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.					
	Authority required Severe active rheumatoid arthritis					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					Price for Max.	Qty	
					\$	\$	

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis,

AND

Patient must have demonstrated an adequate response to treatment with this drug,

AND

Patient must have received this drug as the most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition,

AND

Patient must not receive more than 2 infusions of rituximab under this restriction,

AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

The authority application must be made in writing and must include:

(a) completed authority prescription form(s); and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted within 4 weeks of assessment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

If a patient fails to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

Special Pricing Arrangements apply.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					\$	\$	

restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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Rituximab patients: A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. (2) Swapping therapy. Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled. Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent. A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug. Abatacept patients: Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation. In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment. To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period. To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing. (3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.							
9544H	rituximab 500 mg/50 mL injection, 1 x 50 mL vial	1	..	..	2032.91	Mabthera	RO
THALIDOMIDE <u>Authority required (STREAMLINED)</u> 3342 Multiple myeloma <u>Caution</u> Thalidomide is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment. <u>Note</u> Patients receiving thalidomide under the PBS listing must be registered in the i-access risk management program.							
9667T	thalidomide 100 mg capsule, 28	2	..	..	*1680.00	Thalomid	CJ
9566L	thalidomide 50 mg capsule, 28	4	..	..	*1680.00	Thalomid	CJ

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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MUSCULO-SKELETAL SYSTEM

MUSCLE RELAXANTS

MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS

Other centrally acting agents

BACLOFEN

Authority required (STREAMLINED)

3318

Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity of cerebral origin

Authority required (STREAMLINED)

3319

Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity due to multiple sclerosis

Authority required (STREAMLINED)

3320

Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity due to spinal cord injury

Authority required (STREAMLINED)

3321

Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity due to spinal cord disease

5617P	baclofen 10 mg/5 mL injection: intrathecal, 1 x 5 mL ampoule	10	..	..	*1483.70	Lioresal Intrathecal	NV

DRUGS FOR TREATMENT OF BONE DISEASES

DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

Bisphosphonates

IBANDRONIC ACID

Authority required (STREAMLINED)

3343

Bone metastases from breast cancer

5750P	ibandronic acid 6 mg/6 mL injection, 1 x 6 mL vial	1	11	..	341.36	Bondronat	RO

PAMIDRONATE DISODIUM

Authority required (STREAMLINED)

4433

Hypercalcaemia of malignancy

Clinical criteria:

Patient must have a malignancy refractory to anti-neoplastic therapy.

5667G	pamidronate disodium 15 mg/5 mL injection, 1 x 5 mL vial	4	2	..	*68.64	Pamisol	HH
5669J	pamidronate disodium 60 mg/10 mL injection, 1 x 10 mL vial	1	2	..	68.65	Pamisol	HH

PAMIDRONATE DISODIUM

Authority required (STREAMLINED)

4425

Hypercalcaemia of malignancy

Clinical criteria:

Patient must have a malignancy refractory to anti-neoplastic therapy.

Note

Pharmaceutical benefits that have the form disodium pamidronate powder for I.V. infusion 30 mg (after reconstitution) and pharmaceutical benefits that have the form disodium pamidronate concentrated injection 30 mg are equivalent for the purposes of substitution.

5702D	pamidronate disodium 30 mg injection [2 x 30 mg	1	2	..	68.66 ^a	Aredia 30 mg	NV

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					Qty	\$		
5668H	vials] (&) inert substance diluent [2 x 10 mL ampoules], 1 pack pamidronate disodium 30 mg/10 mL injection, 1 x 10 mL vial	2	2	..	*68.66	^a	Pamisol	HH
PAMIDRONATE DISODIUM <u>Authority required (STREAMLINED)</u> 4421 Hypercalcaemia of malignancy Clinical criteria: Patient must have a malignancy refractory to anti-neoplastic therapy. <u>Authority required (STREAMLINED)</u> 4432 Multiple myeloma <u>Authority required (STREAMLINED)</u> 4426 Bone metastases Clinical criteria: The condition must be due to breast cancer. <u>Note</u> Pharmaceutical benefits that have the form disodium pamidronate powder for I.V. infusion 90 mg (after reconstitution) and pharmaceutical benefits that have the form disodium pamidronate concentrated injection 90 mg are equivalent for the purposes of substitution.								
5703E	pamidronate disodium 90 mg injection [1 x 90 mg vial] (&) inert substance diluent [1 x 10 mL ampoule], 1 pack	1	11	..	102.98	^a	Aredia 90 mg	NV
5670K	pamidronate disodium 90 mg/10 mL injection, 1 x 10 mL vial	1	11	..	102.98	^a	Pamisol	HH
ZOLEDRONIC ACID <u>Authority required (STREAMLINED)</u> 3342 Multiple myeloma <u>Authority required (STREAMLINED)</u> 3343 Bone metastases from breast cancer <u>Authority required (STREAMLINED)</u> 4052 Bone metastases from castration-resistant prostate cancer <u>Authority required (STREAMLINED)</u> 3341 Treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy <u>Note</u> Special Pricing Arrangements apply.								
9653C	zoledronic acid 4 mg/5 mL injection, 1 x 5 mL vial	1	11	..	450.00		Zometa	NV

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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NERVOUS SYSTEM

ANTI-PARKINSON DRUGS

DOPAMINERGIC AGENTS

Dopa and dopa derivatives

LEVODOPA + CARBIDOPA ANHYDROUS

Authority required (STREAMLINED)

3704

Management of advanced Parkinson disease in a patient with severe disabling motor fluctuations not adequately controlled by oral therapy.

Treatment must be commenced in a hospital-based movement disorder clinic

Note

Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

A positive clinical response to Duodopa administered via a temporary nasoduodenal tube should be confirmed before a permanent percutaneous endoscopic gastrostomy (PEG) tube is inserted.

9743T	levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL gel: intestinal, 7 x 100 mL bags	8	5	..	*11536.00	Duodopa	VE

Dopamine agonists

APOMORPHINE

Authority required (STREAMLINED)

4833

Parkinson disease

Clinical criteria:

Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy.

10227G	apomorphine hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules	72	5	..	*3596.40	Apomine	HH
5609F	apomorphine hydrochloride 20 mg/2 mL injection, 5 x 2 mL ampoules	72	5	..	*7196.40	Apomine	HH
5611H	apomorphine hydrochloride 50 mg/10 mL injection: subcutaneous infusion, 5 x 10 mL syringes	36	5	..	*7007.40	Apomine PFS	HH
5610G	apomorphine hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules	36	5	..	*9003.60	Apomine	HH

PSYCHOLEPTICS

ANTIPSYCHOTICS

Diazepines, oxazepines, thiazepines and oxepines

CLOZAPINE

Authority required (STREAMLINED)

4411

Schizophrenia

Clinical criteria:

Patient must be non-responsive to other neuroleptic agents; OR

Patient must be intolerant of other neuroleptic agents.

A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

Note

Patients receiving clozapine under the PBS listing must be registered in a clozapine patient monitoring program; Novartis Clozaril Patient Monitoring System (eCPMS) or Clopineconnect.

5629G	clozapine 100 mg tablet, 100	2	..	..	*242.38	^a Clopine 100	HH
						^a Clozaril 100	NV
5627E	clozapine 200 mg tablet, 100	2	..	..	*484.76	Clopine 200	HH
5628F	clozapine 25 mg tablet, 100	2	..	..	*64.64	^a Clopine 25	HH
						^a Clozaril 25	NV
5626D	clozapine 50 mg tablet, 100	2	..	..	*129.28	Clopine 50	HH

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.	Brand Name and Manufacturer	
					Qty \$		
5630H	clozapine 50 mg/mL oral liquid, 100 mL	1	..	..	135.00	Clopine Suspension	HH

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					\$	\$	

RESPIRATORY SYSTEM

DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

Other systemic drugs for obstructive airway diseases

OMALIZUMAB

Authority required

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment

Clinical criteria:

Patient must be under the care of the same physician for at least 12 months,

AND

Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days,

AND

Patient must have a duration of asthma of at least 1 year,

AND

Patient must have forced expiratory volume (FEV1) less than or equal to 80% predicted, documented on 3 or more occasions in the previous 12 months,

AND

Patient must have past or current evidence of atopy, documented by skin prick testing or RAST,

AND

Patient must have total serum human immunoglobulin E greater than or equal to 76 IU/mL,

AND

Patient must have signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment,

AND

Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented,

AND

Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 12 years or older.

Treatment criteria:

Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Optimised asthma therapy includes:

(i) adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (budesonide 1600 micrograms per day or fluticasone propionate 1000 micrograms per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 micrograms bd or formoterol 12 micrograms bd) for at least 12 months, unless contraindicated or not tolerated, AND

(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application.

The initial IgE assessment must be no more than 12 months old at the time of application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND

(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, must be made at around 22 to 26 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form, which includes the following:
 - (i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and
 - (ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
 - (iii) the signed patient acknowledgement; and
- (c) the IgE pathology report; and
- (d) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms.

Note

The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note

For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note

It is recommended that an application for continuing treatment is submitted at the time of the 22 to 26 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

- (1) How to prescribe PBS-subsidised omalizumab therapy:

- (a) Initial treatment:

Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

- (b) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
	continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.						

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) and oral corticosteroid dose, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note

Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note

Special Pricing Arrangements apply.

Authority required

Uncontrolled severe allergic asthma

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe allergic asthma,

AND

Patient must have demonstrated or sustained an adequate response to treatment with this drug,

AND

Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

An adequate response to omalizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline.

All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, and the assessment of oral corticosteroid dose, must be made at around 18 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form which includes details of maintenance oral corticosteroid dose; and

(c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms.

Note

If the same physician cannot assess the patient please call the Department of Human Services on 1800 700 270.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
					\$	\$	

Note

For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note

It is recommended that an application for continuing treatment is submitted at the time of the 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy:

(a) Initial treatment:

Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

(b) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) and oral corticosteroid dose, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note

Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note

Special Pricing Arrangements apply.

Authority required

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment - balance of supply

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	
	Clinical criteria: Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 28 weeks treatment, AND The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction. Treatment criteria: Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma. Note Authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written application for authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 Note Special Pricing Arrangements apply. Authority required Uncontrolled severe allergic asthma Treatment Phase: Continuing treatment - balance of supply Clinical criteria: Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Treatment criteria: Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma. Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 Note Special Pricing Arrangements apply.					
10109C	omalizumab 150 mg/mL injection, 1 x 1 mL syringe	1	..	..	410.00	Xolair NV

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OMALIZUMAB

Authority required

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment

Clinical criteria:

Patient must be under the care of the same physician for at least 12 months,

AND

Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days,

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
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	AND					
	Patient must have a duration of asthma of at least 1 year,					
	AND					
	Patient must have forced expiratory volume (FEV1) less than or equal to 80% predicted, documented on 3 or more occasions in the previous 12 months,					
	AND					
	Patient must have past or current evidence of atopy, documented by skin prick testing or RAST,					
	AND					
	Patient must have total serum human immunoglobulin E greater than or equal to 76 IU/mL,					
	AND					
	Patient must have signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment,					
	AND					
	Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented,					
	AND					
	Patient must not receive more than 28 weeks of treatment under this restriction.					
	Population criteria:					
	Patient must be aged 12 years or older.					
	Treatment criteria:					
	Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.					
	Optimised asthma therapy includes:					
	(i) adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (budesonide 1600 micrograms per day or fluticasone propionate 1000 micrograms per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 micrograms bd or eformoterol 12 micrograms bd) for at least 12 months, unless contraindicated or not tolerated, AND					
	(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.					
	If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application.					
	The initial IgE assessment must be no more than 12 months old at the time of application.					
	The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:					
	(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND					
	(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.					
	The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, must be made at around 22 to 26 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.					
	This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.					
	A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.					
	At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.					
	The authority application must be made in writing and must include:					
	(a) a completed authority prescription form; and					
	(b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form,					
	which includes the following:					
	(i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and					
	(ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and					
	(iii) the signed patient acknowledgement; and					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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					Price for Max.	Qty	
					\$	\$	

(c) the IgE pathology report; and

(d) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms.

Note

The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note

For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note

It is recommended that an application for continuing treatment is submitted at the time of the 22 to 26 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy:

(a) Initial treatment:

Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

(b) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) and oral corticosteroid dose, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note

Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
					Price for Max.	Qty	
	Special Pricing Arrangements apply.						
	<u>Authority required</u>						
	Uncontrolled severe allergic asthma						
	Treatment Phase: Initial treatment - balance of supply						
	Clinical criteria:						
	Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 28 weeks treatment,						
	AND						
	The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction.						
	Treatment criteria:						
	Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.						
	<u>Note</u>						
	Authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).						
	Written application for authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment should be forwarded to:						
	Department of Human Services						
	Prior Written Approval of Complex Drugs						
	Reply Paid 9826						
	GPO Box 9826						
	HOBART TAS 7001						
	<u>Note</u>						
	Special Pricing Arrangements apply.						
	<u>Authority required</u>						
	Uncontrolled severe allergic asthma						
	Treatment Phase: Continuing treatment						
	Clinical criteria:						
	Patient must have a documented history of severe allergic asthma,						
	AND						
	Patient must have demonstrated or sustained an adequate response to treatment with this drug,						
	AND						
	Patient must not receive more than 24 weeks of treatment under this restriction.						
	Treatment criteria:						
	Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.						
	An adequate response to omalizumab treatment is defined as:						
	(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR						
	(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline.						
	All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, and the assessment of oral corticosteroid dose, must be made at around 18 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.						
	The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.						
	A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.						
	At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy.						
	The authority application must be made in writing and must include:						
	(a) a completed authority prescription form; and						
	(b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form which includes details of maintenance oral corticosteroid dose; and						
	(c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms.						

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer
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					\$	\$	

Note

If the same physician cannot assess the patient please call the Department of Human Services on 1800 700 270.

Note

For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note

It is recommended that an application for continuing treatment is submitted at the time of the 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

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Note

TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy:

(a) Initial treatment:

Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

(b) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) and oral corticosteroid dose, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note

Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note

Special Pricing Arrangements apply.

Authority required

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty	\$	
	Uncontrolled severe allergic asthma						
	Treatment Phase: Continuing treatment - balance of supply						
	Clinical criteria:						
	Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment,						
	AND						
	The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.						
	Treatment criteria:						
	Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.						
	Note						
	Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).						
	Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:						
	Department of Human Services						
	Prior Written Approval of Complex Drugs						
	Reply Paid 9826						
	GPO Box 9826						
	HOBART TAS 7001						
	Note						
	Special Pricing Arrangements apply.						
10118M	omalizumab 75 mg/0.5 mL injection, 1 x 0.5 mL syringe	1	..	..	205.00		Xolair NV

COUGH AND COLD PREPARATIONS

EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS

Mucolytics

DORNASE ALFA

Authority required (STREAMLINED)

4288

Cystic fibrosis

Clinical criteria:

Patient must have a forced vital capacity (FVC) greater than 40% predicted for age, gender and weight,

AND

Patient must have evidence of chronic suppurative lung disease (cough and sputum most days of the week, or greater than 3 respiratory tract infections of more than 2 weeks' duration in any 12 months, or objective evidence of obstructive airways disease).

Population criteria:

Patient must be 5 years of age or older.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. The prescribing of dornase alfa therapy under the HSD program is limited to such physicians. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be by a specialist physician or paediatrician in consultation with such a unit.

The measurement of lung function is to be conducted by independent (other than the treating doctor) experienced personnel at an established lung function testing laboratory, unless this is not possible because of geographical isolation.

Prior to dornase alfa therapy, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with dornase alfa at a dose of 2.5 mg daily.

FEV1 measurement (single test under conditions as above) and a global assessment of the patient involving the patient, the patient's family (in the case of paediatric patients), the treating physician(s) and an additional independent member of the cystic fibrosis treatment team must be undertaken and documented following 3 months of initial therapy.

To be eligible for continued PBS-subsidised treatment with dornase alfa following 3 months of initial treatment:

- (1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND
- (2) the patient or the patient's family (in the case of paediatric patients) must report improvement in the patient's airway clearance; AND
- (3) the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments involving the patient, the patient's family (in the case of paediatric patients), the treating physician(s) and an additional independent member of the cystic fibrosis treatment team must be undertaken and documented at six-monthly intervals to establish that all agree

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	that dornase alfa treatment is continuing to produce worthwhile benefits. Dornase alfa therapy should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.					
	Other aspects of treatment, such as physiotherapy, must be continued.					
	Where there is documented evidence that a patient already receiving dornase alfa therapy would have met the criteria for subsidy, then the patient is eligible to continue treatment under the HSD program. Where such evidence is not available, patients will need to satisfy the initiation and continuation criteria as for new patients. (Four weeks is considered a suitable wash-out period.)					
	<u>Authority required (STREAMLINED)</u>					
	4300					
	Cystic fibrosis					
	Clinical criteria:					
	Patient must have a severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring hospital admissions more frequently than 3 times per year; OR					
	Patient must have significant bronchiectasis on chest high resolution computed tomography scan; OR					
	Patient must have severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; OR					
	Patient must have severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy.					
	Population criteria:					
	Patient must be less than 5 years of age.					
	Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. The prescribing of dornase alfa therapy under the HSD program is limited to such physicians. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be by a specialist physician or paediatrician in consultation with such a unit.					
	Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented involving the patient, the patient's family, the treating physician and an additional independent member of the cystic fibrosis treatment team to establish agreement that dornase alfa treatment is continuing to produce worthwhile benefit. Treatment with dornase alfa should cease if there is not agreement of benefit, as there is always the possibility of harm from unnecessary use. Further reassessments must be undertaken and documented at six-monthly intervals.					
	<u>Authority required (STREAMLINED)</u>					
	4296					
	Cystic fibrosis					
	Treatment Phase: Continuing treatment					
	Clinical criteria:					
	Patient must have initiated treatment with dornase alfa at an age of less than 5 years,					
	AND					
	Patient must have undergone a comprehensive assessment, involving the patient's family, the treating physician and an additional independent member of the cystic fibrosis treatment team which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit.					
	Population criteria:					
	Patient must be 5 years of age or older.					
	Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with dornase alfa should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.					
	<u>Authority required (STREAMLINED)</u>					
	4298					
	Cystic fibrosis					
	Clinical criteria:					
	Patient must have initiated treatment with dornase alfa prior to 1 November 2009,					
	AND					
	Patient must have undergone a comprehensive assessment, involving the patient's family, the treating physician and an additional independent member of the cystic fibrosis treatment team which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit.					
	Population criteria:					
	Patient must be less than 5 years of age.					
	Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with dornase alfa should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.					
	<u>Note</u>					
	Dornase alfa is not PBS-subsidised for use in combination with PBS-subsidised mannitol.					
	<u>Note</u>					
	It is highly desirable that all patients be included in the national cystic fibrosis patient database.					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer	
					Price for Max. Qty \$		
5704F	dornase alfa 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules	2	5	..	*2360.00	Pulmozyme	RO

MANNITOL

Authority required (STREAMLINED)

4299

Cystic fibrosis

Clinical criteria:

Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information mannitol initiation dose assessment, prior to mannitol therapy. If the patient has a negative hyperresponsiveness test they may be eligible for PBS subsidised treatment with mannitol,

AND

Patient must have a forced expiratory volume in 1 second (FEV1) greater than 30% predicted for age, gender and height,

AND

Patient must be intolerant or inadequately responsive to dornase alfa,

AND

Patient must have evidence of chronic suppurative lung disease (cough and sputum most days of the week, or greater than 3 respiratory tract infections of more than 2 weeks' duration in any 12 months, or objective evidence of obstructive airways disease).

Population criteria:

Patient must be 6 years of age or older.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. The prescribing of mannitol therapy under the HSD program is limited to such physicians. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be by a specialist physician or paediatrician in consultation with such a unit.

The measurement of lung function is to be conducted by independent (other than the treating doctor) experienced personnel at an established lung function testing laboratory, unless this is not possible because of geographical isolation.

Prior to mannitol therapy, a baseline measurement of FEV1 must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.

FEV1 measurement (single test under conditions as above) and a global assessment of the patient involving the patient, the patient's family (in the case of paediatric patients), the treating physician(s) and an additional independent member of the cystic fibrosis treatment team must be undertaken and documented following 3 months of initial therapy.

To be eligible for continued PBS-subsidised treatment with mannitol following 3 months of initial treatment:

- (1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND
- (2) the patient or the patient's family (in the case of paediatric patients) must report improvement in the patient's airway clearance; AND
- (3) the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments involving the patient, the patient's family (in the case of paediatric patients), the treating physician(s) and an additional independent member of the cystic fibrosis treatment team must be undertaken and documented at six-monthly intervals to establish that all agree that mannitol treatment is continuing to produce worthwhile benefits. Mannitol therapy should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

Other aspects of treatment, such as physiotherapy, must be continued.

Where there is documented evidence that a patient already receiving mannitol therapy would have met the criteria for subsidy then the patient is eligible to continue treatment under the HSD program. Where such evidence is not available, patients will need to satisfy the initiation and continuation criteria as for new patients. (Four weeks is considered a suitable wash-out period.)

Authority required (STREAMLINED)

4293

Cystic fibrosis

Clinical criteria:

Patient must have initiated treatment with mannitol prior to 1 August 2012,

AND

Patient must have undergone a comprehensive assessment involving the patient's family, the treating physician and an additional independent member of the cystic fibrosis team, which documents agreement that mannitol treatment is continuing to produce a worthwhile benefit.

Population criteria:

Patient must be 6 years of age or older.

Further reassessments are to be undertaken and documented every 6 months. Treatment with mannitol should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.

Note

Mannitol is not PBS-subsidised for use in combination with PBS-subsidised dornase alfa.

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty	Brand Name and Manufacturer	
					\$		
Note It is highly desirable that all patients be included in the national cystic fibrosis patient database.							
2015C	MANNITOL Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers, 1	4	5	..	*1736.00	bronchitol	XA

OTHER RESPIRATORY SYSTEM PRODUCTS

OTHER RESPIRATORY SYSTEM PRODUCTS

Other respiratory system products

IVACAFTOR

Authority required

Cystic fibrosis

Treatment Phase: Initial treatment – New patients

Clinical criteria:

Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit,

AND

Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR

Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele,

AND

Patient must not receive more than 24 weeks of treatment under this restriction,

AND

The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

Patient must be 6 years of age or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Dosage of ivacaftor must not exceed the dose of 150 mg twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of 150 mg daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, ciprofloxacin, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib verapamil.

Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, prednisone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Cystic Fibrosis Ivacaftor Authority Application Supporting Information Form; and
- (3) a signed patient acknowledgement; or an acknowledgement signed by a parent or authorised guardian, if applicable; and
- (4) a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene; and
- (5) the result of a FEV1 measurement performed within a month prior to the date of application. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and
- (6) evidence that the patient has either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities; and
- (7) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and
- (8) a copy of a sweat chloride result; and
- (9) height and weight measurements at the time of application; and
- (10) a baseline measurement of the number of days of hospitalisation (including hospital-in-the home) in the previous 12 months.

Authority required

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty	\$	
	Cystic fibrosis						
	Treatment Phase: Continuing treatment						
	Clinical criteria:						
	Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit,						
	AND						
	Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition,						
	AND						
	Patient must not receive more than 24 weeks of treatment under this restriction,						
	AND						
	The treatment must be given concomitantly with standard therapy for this condition.						
	Population criteria:						
	Patient must be 6 years of age or older.						
	Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.						
	Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.						
	Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation.						
	Dosage of ivacaftor must not exceed the dose of 150 mg twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.						
	Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 28 weeks.						
	Dosage of ivacaftor must not exceed the dose of 150 mg daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, ciprofloxacin, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib verapamil.						
	Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 8 weeks.						
	Ivacaftor is not PBS-subsidised for this condition as a sole therapy.						
	Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:						
	Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort						
	Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin						
	Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, prednisone, rufinamide.						
	The authority application must be in writing and must include:						
	(1) a completed authority prescription form; and						
	(2) a completed Cystic Fibrosis Ivacaftor Authority Continuing Application Supporting Information Form; and						
	(3) the result of a FEV1 measurement performed within one month prior to the date of application. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and						
	(4) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and						
	(5) a recent sweat chloride result; and						
	(6) height and weight measurements at the time of application; and						
	(7) a measurement of number of days of hospitalisation (including hospital in the home) in the previous 6 months.						
	<u>Authority required</u>						
	Cystic fibrosis						
	Treatment Phase: Initial treatment - Grandfather patients						
	Clinical criteria:						
	Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit,						
	AND						
	Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR						
	Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele,						
	AND						
	Patient must have received treatment with ivacaftor for this condition prior to 1 December 2014,						
	AND						

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
	Patient must have received treatment with ivacaftor within the last 6 months at the time of application,					
	AND					
	Patient must not receive more than 24 weeks of treatment under this restriction,					
	AND					
	The treatment must be given concomitantly with standard therapy for this condition.					
	Population criteria:					
	Patient must be 6 years of age or older.					
	Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.					
	Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.					
	Dosage of ivacaftor must not exceed the dose of 150 mg twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.					
	Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 28 weeks.					
	Dosage of ivacaftor must not exceed the dose of 150 mg daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, ciprofloxacin, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib verapamil.					
	Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 8 weeks.					
	Ivacaftor is not PBS-subsidised for this condition as a sole therapy.					
	Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:					
	Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort					
	Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin					
	Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, prednisone, rufinamide.					
	The authority application must be in writing and must include:					
	(1) a completed authority prescription form; and					
	(2) a completed Cystic Fibrosis Ivacaftor Application Supporting Information Form; and					
	(3) a signed patient acknowledgement; or an acknowledgement signed by a parent or authorised guardian, if applicable; and					
	(4) a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene performed prior to commencing treatment with ivacaftor; and					
	(5) the result of a FEV1 measurement performed prior to commencing treatment with ivacaftor for this condition; and					
	(6) the result of a FEV1 measurement performed within a month prior to date of application. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and					
	(7) evidence that the patient had either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities prior to commencing treatment with ivacaftor for this condition; and					
	(8) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and					
	(9) a copy of sweat chloride result performed prior to commencing treatment with ivacaftor for this condition; and					
	(10) a recent sweat chloride result prior to commencing PBS-subsidised ivacaftor; and					
	(11) height and weight measurements at the time of application; and					
	(12) height and weight measurements performed immediately prior to commencement of ivacaftor; and					
	(13) a baseline measurement of number of days of hospitalisation (including hospital-in-the home) in the 12 months prior to commencement of ivacaftor; and					
	(14) a measurement of the number of days of hospitalisation (including hospital-in the home) in the 6 months prior to the date of application; and					
	(15) dates of prior ivacaftor therapy.					
	Note					
	Special Pricing Arrangements apply.					
	Note					
	No increase in the maximum number of repeats may be authorised.					
	Note					
	Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).					
	Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au					
	Applications for authority to prescribe should be forwarded to:					
	Department of Human Services					

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.	Brand Name and Manufacturer	
					Qty \$		
	Prior Written Approval of Complex Drugs						
	Reply Paid 9826						
	GPO Box 9826						
	HOBART TAS 7001						
10170G	ivacaftor 150 mg tablet, 56	1	5	..	22500.00	Kalydeco	VR

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer	
					Price for Max. Qty \$		

VARIOUS

ALL OTHER THERAPEUTIC PRODUCTS

ALL OTHER THERAPEUTIC PRODUCTS

Iron chelating agents

DEFERASIROX

Authority required (STREAMLINED)

3828

Chronic iron overload in patients with disorders of erythropoiesis

Note

Special Pricing Arrangements apply.

5654N	deferasirox 125 mg tablet: dispersible, 28	6	5	..	*1401.48	Exjade	NV
5655P	deferasirox 250 mg tablet: dispersible, 28	6	5	..	*2802.90	Exjade	NV
5656Q	deferasirox 500 mg tablet: dispersible, 28	6	5	..	*5605.80	Exjade	NV

DEFERIPRONE

Authority required (STREAMLINED)

3338

Iron overload in patients with thalassaemia major who are unable to take desferrioxamine therapy

Authority required (STREAMLINED)

3339

Iron overload in patients with thalassaemia major in whom desferrioxamine therapy has proven ineffective

5658T	deferiprone 100 mg/mL oral liquid, 250 mL	5	5	..	*1126.40	Ferriprox	TX
5657R	deferiprone 500 mg tablet, 100	6	5	..	*2703.36	Ferriprox	TX

DEFERRIOXAMINE

Authority required (STREAMLINED)

3340

Disorders of erythropoiesis associated with treatment-related chronic iron overload

5661Y	desferrioxamine mesylate 2 g injection, 1 x 2 g vial	60	5	..	*1724.40	^a Hospira Pty Limited	HH
5662B	desferrioxamine mesylate 500 mg injection, 10 x 500 mg vials	40	5	^B 17.40	*1741.80	^a Desferal 2 g	NV
				..	*2874.40	^a Hospira Pty Limited	HH
				^B 238.40	*3112.80	^a Desferal 500 mg	NV

Drugs for treatment of hyperkalemia and hyperphosphatemia

LANTHANUM

Authority required (STREAMLINED)

4832

Hyperphosphataemia

Treatment Phase: Initiation and stabilisation

Clinical criteria:

The condition must not be adequately controlled by calcium,

AND

Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR

The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy,

AND

The treatment must not be used in combination with any other phosphate binding agents.

Treatment criteria:

Patient must be undergoing dialysis for chronic kidney disease.

5782H	LANTHANUM Tablet, chewable, 1000 mg (as carbonate hydrate), 90	2	5	..	*890.02	Fosrenol	ZI

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty	Brand Name and Manufacturer	
					\$		
5780F	LANTHANUM Tablet, chewable, 500 mg (as carbonate hydrate), 90	2	5	..	*523.54	Fosrenol	ZI
5781G	LANTHANUM Tablet, chewable, 750 mg (as carbonate hydrate), 90	2	5	..	*790.56	Fosrenol	ZI

SEVELAMER

Authority required (STREAMLINED)

4832

Hyperphosphataemia

Treatment Phase: Initiation and stabilisation

Clinical criteria:

The condition must not be adequately controlled by calcium,

AND

Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR

The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy,

AND

The treatment must not be used in combination with any other phosphate binding agents.

Treatment criteria:

Patient must be undergoing dialysis for chronic kidney disease.

9546K	sevelamer hydrochloride 800 mg tablet, 180	2	5	..	*620.00	Renagel	GZ

SUCROFERRIC OXYHYDROXIDE

Authority required (STREAMLINED)

4832

Hyperphosphataemia

Treatment Phase: Initiation and stabilisation

Clinical criteria:

The condition must not be adequately controlled by calcium,

AND

Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR

The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy,

AND

The treatment must not be used in combination with any other phosphate binding agents.

Treatment criteria:

Patient must be undergoing dialysis for chronic kidney disease.

10233N	iron (as sucroferric oxyhydroxide) 500 mg tablet: chewable, 90	2	5	..	*753.46	Velphoro	FN

SECTION 100 (BOTULINUM TOXIN PROGRAM)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	Price ex manufacturer \$	Brand Name and Manufacturer
	BOTULINUM TOXIN TYPE A			
	<u>Criteria for availability</u>			
	Blepharospasm or hemifacial spasm			
	Population criteria:			
	Patient must be aged 12 years or older.			
	<u>Note</u>			
	Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.			
	<u>Note</u>			
	The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.			
	<u>Criteria for availability</u>			
	Dynamic equinus foot deformity			
	Clinical criteria:			
	The condition must be due to spasticity,			
	AND			
	Patient must be an ambulant cerebral palsy patient.			
	Population criteria:			
	Patient must be aged from 2 to 17 years inclusive.			
	<u>Note</u>			
	Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.			
	<u>Note</u>			
	The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.			
	<u>Criteria for availability</u>			
	Dynamic equinus foot deformity			
	Clinical criteria:			
	The condition must be due to spasticity,			
	AND			
	Patient must be an ambulant cerebral palsy patient,			
	AND			
	Patient must have commenced on PBS-subsidised treatment with botulinum toxin type A purified neurotoxin complex as a paediatric patient.			
	Population criteria:			
	Patient must be aged 18 years or older.			
	<u>Note</u>			
	Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.			
	<u>Note</u>			
	The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.			
	<u>Criteria for availability</u>			
	Spasmodic torticollis			
	Clinical criteria:			
	The treatment must be as monotherapy; OR			
	The treatment must be as adjunctive therapy to current standard care.			
	<u>Note</u>			
	Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.			
	<u>Note</u>			
	The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.			
	<u>Criteria for availability</u>			
	Moderate to severe spasticity of the upper limb			
	Clinical criteria:			
	Patient must have cerebral palsy.			
	Population criteria:			
	Patient must be aged from 2 to 17 years inclusive.			
	<u>Note</u>			

SECTION 100 (BOTULINUM TOXIN PROGRAM)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	Price ex manufacturer \$	Brand Name and Manufacturer
	Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270. Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent. Criteria for availability Moderate to severe spasticity of the upper limb Clinical criteria: Patient must have cerebral palsy, AND Patient must have commenced on PBS-subsidised treatment with botulinum toxin type A purified neurotoxin complex as a paediatric patient. Population criteria: Patient must be aged 18 years or older. Note Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270. Note Contact the Department of Human Services before commencing PBS-subsidised treatment in cerebral palsy patients who have been treated for moderate to severe spasticity of the upper limb with non-PBS-subsidised botulinum toxin prior to the age of 18. Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent. Criteria for availability Moderate to severe spasticity of the upper limb following a stroke Clinical criteria: The treatment must be used as second line therapy when standard management has failed (e.g. physiotherapy and/or oral spasticity agents) or as an adjunct to physical therapy. Population criteria: Patient must be an adult. Moderate to severe spasticity is defined as MAS greater than or equal to 3 using modified Ashworth scale. Maximum number of treatments to be authorised is 4 (total Xeomin®, Botox® and Dysport®) per upper limb per lifetime. Treatment should not be initiated until 3 months post-stroke in patients who do not have established severe contracture. Treatment should be discontinued if the patient does not respond (decrease of MAS greater than 1 in at least one joint) after two treatments. The date of the stroke must be provided. Contraindications to treatment include established severe contracture and known sensitivity to botulinum toxin. Note Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270. Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent. Criteria for availability Severe primary axillary hyperhidrosis Clinical criteria: Patient must have previously failed or be intolerant to topical aluminium chloride hexahydrate after one to two months of treatment. Population criteria: Patient must be aged 12 years or older. Maximum number of treatments per year is 3, with no less than 4 months to elapse between treatments. Note Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270. Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent. Note Special Pricing Arrangements apply. Criteria for availability Urinary incontinence Clinical criteria: The condition must be due to neurogenic detrusor overactivity, as demonstrated by urodynamic study,			

SECTION 100 (BOTULINUM TOXIN PROGRAM)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	Price ex manufacturer \$	Brand Name and Manufacturer
	AND The condition must be inadequately controlled by anti-cholinergic therapy, AND Patient must experience at least 14 episodes of urinary incontinence per week prior to commencement of treatment with botulinum toxin, AND The treatment must not continue if the patient does not achieve a 50% or greater reduction from baseline in urinary incontinence episodes 6-12 weeks after the first treatment, AND Patient must be willing and able to self-catheterise. Population criteria: Patient must have multiple sclerosis; OR Patient must have a spinal cord injury; OR Patient must be aged 18 years or older and have spina bifida. Note Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270. Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent. Note Special Pricing Arrangements apply. Criteria for availability Chronic migraine Clinical criteria: Patient must have experienced an average of 15 or more headache days per month, with at least 8 days of migraine, over a period of at least 6 months, prior to commencement of treatment with botulinum toxin, AND Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with botulinum toxin, AND Patient must have achieved and maintained a 50% or greater reduction from baseline in the number of headache days per month after two treatment cycles (each of 12 weeks duration) in order to be eligible for continuing PBS-subsidised treatment. Population criteria: Patient must be an adult. Medication overuse headache must be appropriately managed prior to initiation of treatment with botulinum toxin. Note Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270. Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent. Note Special Pricing Arrangements apply. Criteria for availability Urinary incontinence Clinical criteria: The condition must be due to idiopathic overactive bladder, AND The condition must have been inadequately controlled by therapy involving at least two alternative anti-cholinergic agents, AND Patient must experience at least 14 episodes of urinary incontinence per week prior to commencement of treatment with botulinum toxin, AND The treatment must not continue if the patient does not achieve a 50% or greater reduction from baseline in urinary incontinence episodes 6-12 weeks after the first treatment, AND Patient must be willing and able to self-catheterise. Population criteria:			

SECTION 100 (BOTULINUM TOXIN PROGRAM)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	Price ex manufacturer \$	Brand Name and Manufacturer	
	Patient must be aged 18 years or older.				
	Note Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270. Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent. Note Special Pricing Arrangements apply.				
6103F	botulinum toxin type A 100 units injection, 1 x 100 units vial	1	415.50	Botox	AG

CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX

Criteria for availability

Moderate to severe spasticity of the upper limb following a stroke

Clinical criteria:

The treatment must be used as second line therapy when standard management has failed (e.g. physiotherapy and/or oral spasticity agents) or as an adjunct to physical therapy.

Population criteria:

Patient must be an adult.

Moderate to severe spasticity is defined as MAS greater than or equal to 3 using modified Ashworth scale.

Maximum number of treatments to be authorised is 4 (total Xeomin®, Botox® and Dysport®) per upper limb per lifetime. Treatment should not be initiated until 3 months post-stroke in patients who do not have established severe contracture. Treatment should be discontinued if the patient does not respond (decrease of MAS greater than 1 in at least one joint) after two treatments.

The date of the stroke must be provided.

Contraindications to treatment include established severe contracture and known sensitivity to botulinum toxin.

Note

Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.

Note

The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Criteria for availability

Dynamic equinus foot deformity

Clinical criteria:

The condition must be due to spasticity,

AND

Patient must be an ambulant cerebral palsy patient.

Population criteria:

Patient must be aged from 2 to 17 years inclusive.

Note

Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.

Note

The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Criteria for availability

Dynamic equinus foot deformity

Clinical criteria:

The condition must be due to spasticity,

AND

Patient must be an ambulant cerebral palsy patient,

AND

Patient must have commenced on PBS-subsidised treatment with clostridium botulinum type A toxin-haemagglutinin complex as a paediatric patient.

Population criteria:

Patient must be aged 18 years or older.

Note

The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Note

SECTION 100 (BOTULINUM TOXIN PROGRAM)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	Price ex manufacturer \$	Brand Name and Manufacturer	
	Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270. <u>Criteria for availability</u> Spasmodic torticollis Clinical criteria: The treatment must be as monotherapy; OR The treatment must be as adjunctive therapy to current standard care. <u>Note</u> Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270. <u>Note</u> The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent. <u>Criteria for availability</u> Blepharospasm or hemifacial spasm Population criteria: Patient must be an adult. <u>Note</u> The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent. <u>Note</u> Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.				
1152P	clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 x 300 units vial	1	361.52	Dysport	IS
6293F	clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 x 500 units vial	1	644.81	Dysport	IS
	INCOBOTULINUMTOXINA <u>Criteria for availability</u> Spasmodic torticollis Clinical criteria: The treatment must be as monotherapy; OR The treatment must be as adjunctive therapy to current standard care. <u>Criteria for availability</u> Blepharospasm Population criteria: Patient must be an adult. <u>Criteria for availability</u> Moderate to severe spasticity of the upper limb following a stroke Clinical criteria: The treatment must be used as second line therapy when standard management has failed (e.g. physiotherapy and/or oral spasticity agents) or as an adjunct to physical therapy. Population criteria: Patient must be an adult. Moderate to severe spasticity is defined as MAS greater than or equal to 3 using modified Ashworth scale. Maximum number of treatments to be authorised is 4 (total Xeomin®, Botox® and Dysport®) per upper limb per lifetime. Treatment should not be initiated until 3 months post-stroke in patients who do not have established severe contracture. Treatment should be discontinued if the patient does not respond (decrease of MAS greater than 1 in at least one joint) after two treatments. The date of the stroke must be provided. Contraindications to treatment include established severe contracture and known sensitivity to botulinum neurotoxin. <u>Note</u> Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270. <u>Note</u> The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.				
10253P	incobotulinumtoxinA 100 mouse LD50 units injection, 1 x 100 mouse LD50 units vial	1	375.00	Xeomin	EZ

SECTION 100 (HUMAN GROWTH HORMONE)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	Price ex manufacturer \$	Brand Name and Manufacturer	
SOMATROPIN					
<u>Criteria for availability</u>					
Short stature in accordance with the 'Guidelines for the Pharmaceutical Benefits Scheme Growth Hormone Program. The program also aims to correct neonatal hypoglycaemia due to biochemical growth hormone deficiency and improve body composition for children with Prader-Willi Syndrome.					
The Guidelines specify the eligibility criteria for the conditions that are eligible for treatment through the program which include:					
(i) short stature and slow growth;					
(ii) short stature associated with biochemical growth hormone deficiency;					
(iii) growth retardation secondary to intracranial lesion or cranial irradiation;					
(iv) neonates/infants at risk of hypoglycaemia secondary to growth hormone deficiency;					
(v) short stature associated with Turner Syndrome;					
(vi) short stature due to short stature homeobox (SHOX) gene disorders;					
(vii) short stature associated with chronic renal insufficiency;					
(viii) biochemical growth hormone deficiency and precocious puberty;					
(ix) Prader-Willi syndrome.					
Genotropin branded products are available for the treatment of Prader-Willi Syndrome in accordance with the Guidelines					
<u>Note</u>					
Growth hormone (Somatropin) for adults is currently not subsidised through the Pharmaceutical Benefits Scheme.					
These guidelines may be obtained from the Department of Health and Ageing's internet site at http://www.health.gov.au/hGH , or from:					
Growth Hormone Program					
Access and Systems Branch					
Department of Health and Ageing					
GPO Box 9848					
CANBERRA ACT 2601					
Contact telephone number (02) 6289 7274					
6329D	SOMATROPIN (Recombinant human growth hormone) Injection 8 mg (24 i.u.) vial with 1.37 mL diluent cartridge (with preservative) (for use with one.click auto-injector), 1	1	396.00	Saizen 8 mg click.easy	SG
9586M	SOMATROPIN (Recombinant human growth hormone) Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative), 1	1	594.00	Genotropin GoQuick	PF
9585L	SOMATROPIN (Recombinant human growth hormone) Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative), 1	1	247.50	Genotropin GoQuick	PF
9628R	somatropin 1.8 international units (600 microgram) injection [7 x 600 microgram syringes] (& inert substance diluent [7 x 0.25 mL syringes], 1 pack	1	207.90	Genotropin MiniQuick	PF
6266T	somatropin 12 international units (4 mg) injection [1 x 4 mg vial] (& inert substance diluent [1 vial], 1 pack	1	198.00	Zomacton	FP
6295H	somatropin 15 international units (5 mg/1.5 mL) injection, 1 x 1.5 mL cartridge	1	247.50	Norditropin SimpleXx	NO
6476W	somatropin 15 international units (5 mg/1.5 mL) injection, 1 x 1.5 mL cartridge	1	247.50	Omnitrope	SZ
6169Q	somatropin 18 international units (6 mg) injection [1 x 6 mg cartridge] (& inert substance diluent [1 x 3.15 mL syringe], 1 pack	1	297.00	Humatrope	LY
5822K	somatropin 18 international units (6 mg/1.03 mL) injection, 1 x 1.03 mL cartridge	1	297.00	Saizen	SG
6313G	somatropin 2.4 international units (800 microgram) injection [7 x 800 microgram syringes] (& inert substance diluent [7 x 0.25 mL syringes], 1 pack	1	277.20	Genotropin MiniQuick	PF
6314H	somatropin 3 international units (1 mg) injection [7 x 1 mg syringes] (& inert substance diluent [7 x 0.25 mL syringes], 1 pack	1	346.50	Genotropin MiniQuick	PF
6315J	somatropin 3.6 international units (1.2 mg) injection [7 x 1.2 mg syringes] (& inert substance diluent [7 x 0.25 mL syringes], 1 pack	1	415.80	Genotropin MiniQuick	PF
6310D	somatropin 30 international units (10 mg) injection [1 x 10 mg vial] (& inert substance diluent [1 x 1 mL syringe], 1 pack	1	495.00	Zomacton	FP
6296J	somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge	1	495.00	Norditropin SimpleXx	NO
6311E	somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge	1	495.00	Omnitrope	SZ

SECTION 100 (HUMAN GROWTH HORMONE)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	Price ex manufacturer \$	Brand Name and Manufacturer	
9604L	somatropin 30 international units (10 mg/2 mL) injection, 1 x 2 mL cartridge	1	495.00	NutropinAq	IS
6312F	somatropin 36 international units (12 mg) injection [1 x 12 mg cartridge] (&) inert substance diluent [1 x 1 mL cartridge], 1 pack	1	594.00	Genotropin	PF
6170R	somatropin 36 international units (12 mg) injection [1 x 12 mg cartridge] (&) inert substance diluent [1 x 3.15 mL syringe], 1 pack	1	594.00	Humatrope	LY
5824M	somatropin 36 international units (12 mg/1.5 mL) injection, 1 x 1.5 mL cartridge	1	594.00	Saizen	SG
6316K	somatropin 4.2 international units (1.4 mg) injection [7 x 1.4 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack	1	485.10	Genotropin MiniQuick	PF
6317L	somatropin 4.8 international units (1.6 mg) injection [7 x 1.6 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack	1	554.40	Genotropin MiniQuick	PF
6297K	somatropin 45 international units (15 mg/1.5 mL) injection, 1 x 1.5 mL cartridge	1	742.50	Norditropin SimpleXx	NO
6318M	somatropin 5.4 international units (1.8 mg) injection [7 x 1.8 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack	1	623.70	Genotropin MiniQuick	PF
6319N	somatropin 6 international units (2 mg) injection [7 x 2 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack	1	693.00	Genotropin MiniQuick	PF
3388H	somatropin 60 international units (20 mg/2.5 mL) injection, 1 x 2.5 mL cartridge	1	990.00	Saizen	SG
6345Y	somatropin 72 international units (24 mg) injection [1 x 24 mg cartridge] (&) inert substance diluent [1 x 3.15 mL syringe], 1 pack	1	1188.00	Humatrope	LY

SOMATROPIN

Criteria for availability

Short stature in accordance with the 'Guidelines for the Pharmaceutical Benefits Scheme Growth Hormone Program. The program also aims to correct neonatal hypoglycaemia due to biochemical growth hormone deficiency and improve body composition for children with Prader-Willi Syndrome.

The Guidelines specify the eligibility criteria for the conditions that are eligible for treatment through the program which include:

- (i) short stature and slow growth;
- (ii) short stature associated with biochemical growth hormone deficiency;
- (iii) growth retardation secondary to intracranial lesion or cranial irradiation;
- (iv) neonates/infants at risk of hypoglycaemia secondary to growth hormone deficiency;
- (v) short stature associated with Turner Syndrome;
- (vi) short stature due to short stature homeobox (SHOX) gene disorders;
- (vii) short stature associated with chronic renal insufficiency;
- (viii) biochemical growth hormone deficiency and precocious puberty;
- (ix) Prader-Willi syndrome.

Genotropin branded products are available for the treatment of Prader-Willi Syndrome in accordance with the Guidelines

Note

Growth hormone (Somatropin) for adults is currently not subsidised through the Pharmaceutical Benefits Scheme.

These guidelines may be obtained from the Department of Health and Ageing's internet site at <http://www.health.gov.au/hGH>, or from:

Growth Hormone Program

Access and Systems Branch

Department of Health and Ageing

GPO Box 9848

CANBERRA ACT 2601

Contact telephone number (02) 6289 7274

Note

Special Pricing Arrangements apply.

5818F	somatropin 15 international units (5 mg/1.5 mL) injection, 1 x 1.5 mL cartridge	1	315.50	Norditropin FlexPro	NO
5819G	somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge	1	631.00	Norditropin FlexPro	NO
5820H	somatropin 45 international units (15 mg/1.5 mL) injection, 1 x 1.5 mL cartridge	1	946.50	Norditropin FlexPro	NO

SECTION 100 (IVF/GIFT TREATMENT)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	Price ex manufacturer \$	Brand Name and Manufacturer	
CETRORELIX					
<u>Criteria for availability</u>					
For the prevention of premature luteinisation and ovulation in patients undergoing controlled ovarian stimulation, followed by oocyte pick-up and assisted reproductive techniques as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule					
<u>Note</u>					
Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact Medicare Australia on 1800 700 270.					
9599F	cetrorelix 250 microgram injection [1 x 250 microgram vial] (&) inert substance diluent [1 x 1 mL syringe], 1 pack	1	46.08	Cetrotide	SG
CHORIOGONADOTROPIN ALFA					
<u>Criteria for availability</u>					
Patients who are receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule					
<u>Note</u>					
Supply of this item is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact Medicare Australia on 1800 700 270.					
<u>Note</u>					
Special Pricing Arrangements apply.					
6182J	choriogonadotropin alfa 250 microgram/0.5 mL injection, 1 x 0.5 mL cartridge	1	54.80	Ovidrel	SG
9631X	choriogonadotropin alfa 250 microgram/0.5 mL injection, 1 x 0.5 mL syringe	1	54.80	Ovidrel	SG
CORIFOLLITROPIN ALFA					
<u>Criteria for availability</u>					
Controlled ovarian stimulation					
Clinical criteria:					
Patient must have an antral follicle count of 20 or less.					
Treatment criteria:					
Patient must be undergoing treatment as described in items 13200, 13201 or 13202 of the Health Insurance (General Medical Services Table) Regulations,					
AND					
Patient must be undergoing a gonadotrophin releasing hormone antagonist cycle.					
<u>Note</u>					
Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact the Department of Human Services on 1800 700 270.					
5816D	corifollitropin alfa 100 microgram/0.5 mL injection, 1 x 0.5 mL syringe	1	410.14	Elonva	MK
5817E	corifollitropin alfa 150 microgram/0.5 mL injection, 1 x 0.5 mL syringe	1	673.51	Elonva	MK
FOLLITROPIN ALFA					
<u>Criteria for availability</u>					
Patients who are receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule					
<u>Note</u>					
Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact Medicare Australia on 1800 700 270.					
6431L	follitropin alfa 300 international units / 0.5 mL (21.84 microgram/0.5 mL) injection, 1 x 0.5 mL cartridge	1	145.20	Gonal-f Pen	SG
6432M	follitropin alfa 450 international units / 0.75 mL (32.76 microgram/0.75 mL) injection, 1 x 0.75 mL cartridge	1	217.80	Gonal-f Pen	SG
6433N	follitropin alfa 900 international units / 1.5 mL (65.52 microgram/1.5 mL) injection, 1 x 1.5 mL cartridge	1	435.60	Gonal-f Pen	SG
FOLLITROPIN BETA					
<u>Criteria for availability</u>					
Patients who are receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule					
<u>Note</u>					
Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact Medicare Australia on 1800 700 270.					
6335K	follitropin beta 300 international units/0.36 mL injection, 1 x 0.36 mL	1	150.00	Puregon 300 IU/0.36	MK

SECTION 100 (IVF/GIFT TREATMENT)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	Price ex manufacturer \$	Brand Name and Manufacturer	
6336L	cartridge follitropin beta 600 international units/0.72 mL injection, 1 x 0.72 mL	1	292.72	Puregon 600 IU/0.72 mL	MK
6464F	cartridge follitropin beta 900 international units/1.08 mL injection, 1 x 1.08 mL	1	435.15	Puregon 900 IU/1.08 mL	MK

GANIRELIX

Criteria for availability

For the prevention of premature luteinisation and ovulation in patients undergoing controlled ovarian stimulation, followed by oocyte pick-up and assisted reproductive techniques as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule

Note

Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact Medicare Australia on 1800 700 270.

9583J	ganirelix 250 microgram/0.5 mL injection, 1 x 0.5 mL syringe	1	46.08	Orgalutran	MK
9584K	ganirelix 250 microgram/0.5 mL injection, 5 x 0.5 mL syringes	1	230.40	Orgalutran	MK

GONADOTROPHIN CHORIONIC HUMAN

Criteria for availability

Patients who are receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule

Note

Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact Medicare Australia on 1800 700 270.

6178E	gonadotrophin chorionic human 1500 international units injection [3 x 1500 international units ampoules] (&) inert substance diluent [3 x 1 mL ampoules], 1 pack	1	39.57	Pregnyl	MK
6181H	gonadotrophin chorionic human 5000 international units injection [1 x 5000 international units ampoule] (&) inert substance diluent [1 x 1 mL ampoule], 1 pack	1	11.49	Pregnyl	MK

GONADOTROPHIN-MENOPAUSAL HUMAN

Criteria for availability

Patients who are receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule

Note

Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact Medicare Australia on 1800 700 270.

2038G	gonadotrophin-menopausal human 1200 international units injection [1 x 1200 international units vial] (&) inert substance diluent [2 x 1 mL syringes], 1 pack	1	531.18	Menopur 1200	FP
2036E	gonadotrophin-menopausal human 600 international units injection [1 x 600 international units vial] (&) inert substance diluent [1 x 1 mL syringe], 1 pack	1	265.59	Menopur 600	FP

NAFARELIN

Criteria for availability

For the prevention of premature luteinisation and ovulation in patients undergoing controlled ovarian stimulation, followed by oocyte pick-up and assisted reproductive techniques as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule

Note

Supply of this item is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact Medicare Australia on 1800 700 270.

5815C	nafarelin 200 microgram/actuation nasal spray, 60 actuations	1	106.00	Synarel	PF

PROGESTERONE

Criteria for availability

Luteal support as part of an assisted reproductive technology (ART) treatment programme for infertile women

Clinical criteria:

The treatment must be for luteal phase support,

AND

Patient must be receiving medical treatment as described in items 13200 or 13201 of the Health Insurance (General Medical Services Table) Regulations.

The luteal phase is defined as the time span from embryo transfer until implantation confirmed by positive B-hCG measurement.

Note

SECTION 100 (IVF/GIFT TREATMENT)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	Price ex manufacturer \$	Brand Name and Manufacturer	
Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact the Department of Human Services on 1800 700 270.					
9608Q	progesterone 100 mg pessary, 15	1	50.40	Oipro	ON
10116K	progesterone 100 mg pessary, 21	1	49.39	Endometrin	FP
9609R	progesterone 200 mg pessary, 15	1	55.60	Oipro	ON

PROGESTERONE

Criteria for availability

Luteal support as part of an assisted reproductive technology (ART) treatment programme for infertile women

Clinical criteria:

The treatment must be for luteal phase support,

AND

Patient must be receiving medical treatment as described in items 13200 or 13201 of the Health Insurance (General Medical Services Table) Regulations.

The luteal phase is defined as the time span from embryo transfer until implantation confirmed by positive B-hCG measurement.

Note

Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact the Department of Human Services on 1800 700 270.

Note

Special Pricing Arrangements apply.

6366C	progesterone 8% vaginal gel, 15 applications	1	148.50	Crinone 8%	SG

OPIATE DEPENDENCE TREATMENT PROGRAM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	Price ex manufacturer \$	Brand Name and Manufacturer	
BUPRENORPHINE					
<u>Criteria for availability</u>					
Treatment of opiate dependence, including maintenance and detoxification (withdrawal), within a framework of medical, social and psychological treatment					
<u>Note</u>					
Treatment must be in accordance with the law of the relevant State or Territory.					
<u>Note</u>					
Shared Care Model:					
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.					
6308B NP	buprenorphine 2 mg tablet, 7	1	10.50	Subutex	RC
6307Y NP	buprenorphine 400 microgram tablet, 7	1	6.16	Subutex	RC
6309C NP	buprenorphine 8 mg tablet, 7	1	30.10	Subutex	RC
BUPRENORPHINE + NALOXONE					
<u>Criteria for availability</u>					
Treatment of opiate dependence within a framework of medical, social and psychological treatment					
<u>Caution</u>					
Buprenorphine with naloxone soluble film and buprenorphine with naloxone sublingual tablet do not meet all the criteria for bioequivalence. Patients being switched between sublingual tablets and soluble films may therefore require a dosage adjustment.					
<u>Note</u>					
Treatment must be in accordance with the law of the relevant State or Territory.					
<u>Note</u>					
Shared Care Model:					
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.					
9749D NP	buprenorphine 2 mg + naloxone 500 microgram film: sublingual, 28 films	1	46.20	Suboxone Film 2/0.5	RC
9750E NP	buprenorphine 8 mg + naloxone 2 mg film: sublingual, 28 films	1	132.44	Suboxone Film 8/2	RC
METHADONE					
<u>Criteria for availability</u>					
Treatment of opiate dependence in accordance with the law of the relevant State or Territory					
<u>Caution</u>					
The risk of drug dependence is high.					
<u>Note</u>					
Shared Care Model:					
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.					
6172W NP	methadone hydrochloride 5 mg/mL oral liquid, 1000 mL	1	33.20	^a Aspen Methadone Syrup	QA
				^a Biodone Forte	MW
6171T NP	methadone hydrochloride 5 mg/mL oral liquid, 200 mL	1	7.91	^a Aspen Methadone Syrup	QA
				^a Biodone Forte	MW

Section 3 – Container Prices, Fees, Standard Packs and Prices for Ready Prepared Pharmaceutical Benefits

CONTAINER PRICES FOR QUANTITIES OF READY PREPARED BENEFITS LESS THAN THE STANDARD PACK:

Injectables	150 mL vial	\$0.81
Other Items	25 mL vial	\$0.32

(The 25 mL is the most commonly used size)

FEES:

Dispensing Fee for Ready Prepared Benefits	\$6.76
Dangerous Drug Fee	\$2.71
Additional Fee for Agreed Price Ready Prepared Benefits	\$1.15

NOTE -

Standard packs and prices (including mark-up, but without dispensing fee and dangerous drug fee) are for items against the price of which an asterisk () is shown in Section 2 of the Schedule.*

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name, Form/Strength	Pack and Price	Manufacturer
8048N	abciximab 10 mg/5 mL injection, 1 x 5 mL vial	1@ 482.23	LY
1003T	aciclovir 200 mg tablet, 25	25@ 12.83	AF, GN, SZ
1003T	aciclovir 200 mg tablet, 25	25@ 13.86	GK
2014B	alginate sodium 500 mg/10 mL + calcium carbonate 160 mg/10 mL + sodium bicarbonate 267 mg/10 mL oral liquid, 500 mL	1@ 4.13	RC
1557Y	allopurinol 100 mg tablet, 100	100@ 2.28	AF
2159P	aluminium hydroxide 250 mg/5 mL + magnesium hydroxide 120 mg/5 mL + magnesium trisilicate 120 mg/5 mL oral liquid, 500 mL	1@ 5.64	FM
2157M	ALUMINIUM HYDROXIDE with MAGNESIUM HYDROXIDE Oral suspension 200 mg-200 mg per 5 mL, 500 mL, 1	1@ 5.64	JT
3417W	amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without methionine and supplemented with docosahexaenoic acid oral liquid, 36 x 125 mL cans	1@ 625.39	SB
9330C	amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine and tyrosine, and supplemented with docosahexaenoic acid oral liquid, 36 x 125 mL cans	1@ 625.39	SB
8678R	amino acid formula without phenylalanine 1 g tablet, 75	1@ 59.19	SB
8554F	amino acid formula without phenylalanine 500 mg capsule, 200	1@ 79.37	SB
2347M	amino acid formula without phenylalanine oral liquid: powder for, 30 x 20 g sachets	1@ 208.07	SB
10161T	amino acid formula without valine, leucine and isoleucine containing 5 g of protein equivalent oral liquid: powder for, 30 x 6 g sachets	1@ 257.66	VF
8479G	amino acid formula with vitamins, minerals and long chain polyunsaturated fatty acids without phenylalanine oral liquid: powder for, 400 g	1@ 87.15	SB
9438R	amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 30 x 24 g sachets	1@ 526.99	VF
5484P	amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 30 x 25 g sachets	1@ 787.00	VF
2650L	amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 400 g	1@ 95.36	SB
2646G	amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 500 g	1@ 222.29	SB
3444G	amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 30 x 24 g sachets	1@ 526.99	VF
3443F	amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 30 x 25 g sachets	1@ 772.99	VF
8058D	amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 400 g	1@ 95.36	SB
8059E	amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 500 g	1@ 222.29	SB
8061G		1@ 337.29	SB
1923F	AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE, THREONINE and VALINE and low in ISOLEUCINE Oral liquid 130 mL, 30, 1	1@ 772.99	VF
9133Q	amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 130 mL cans	1@ 772.99	VF
2640Y	amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 174 mL sachets	1@ 1018.99	VF
2639X	amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 87 mL sachets	1@ 526.99	VF
8677Q	amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 30 x 24 g sachets	1@ 526.99	VF
8744F	amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 30 x 25 g sachets	1@ 772.99	VF
8417B	amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 400 g	1@ 95.36	SB
8328H	amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 500 g	1@ 222.29	SB
8416Y		1@ 337.29	SB
1548L	AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE Oral liquid 125 mL, 30, 1	1@ 1030.64	SB
9132P	amino acid formula with vitamins and minerals without phenylalanine	1@ 772.99	VF

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name, Form/Strength	Pack and Price	Manufacturer
2701E	and tyrosine oral liquid, 30 x 130 mL cans amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 174 mL sachets	1@ 1018.99	VF
2674R	amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 87 mL sachets	1@ 526.99	VF
8631G	amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 30 x 24 g sachets	1@ 526.99	VF
8667E	amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 30 x 25 g sachets	1@ 772.99	VF
9395L	amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 30 x 29 g sachets	1@ 448.51	SB
8445L	amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 400 g	1@ 95.36	SB
3078B	amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 500 g	1@ 337.29	SB
8446M		1@ 222.29	SB
1547K	AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE and TYROSINE Oral liquid 125 mL, 30, 1	1@ 1030.64	SB
8746H	amino acid formula with vitamins and minerals without phenylalanine oral liquid, 18 x 250 mL cans	18@ 261.37	SB
9021T	amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 125 mL cans	1@ 514.34	SB
8846N	amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 130 mL cans	1@ 385.48	VF
2474F	amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 174 mL cans	1@ 511.90	VF
5483N	amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 85 g sachets	1@ 263.05	VF
2382J	amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 87 mL cans	1@ 257.09	VF
9396M	amino acid formula with vitamins and minerals without phenylalanine oral liquid, 36 x 125 mL cans	1@ 315.86	SB
9397N	amino acid formula with vitamins and minerals without phenylalanine oral liquid, 60 x 62.5 mL cans	1@ 526.47	SB
8555G	amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 24 g sachets	1@ 263.05	VF
8591E	amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 25 g sachets	1@ 385.68	VF
8804J	amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 27.8 g sachets	1@ 514.34	SB
8613H	amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 29 g sachets	1@ 221.42	SB
8727H	amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 50 g sachets	1@ 501.88	SB
2738D	amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 500 g	1@ 109.70	SB
2739E		1@ 168.25	SB
2806Q	amino acid formula with vitamins and minerals without phenylalanine oral semi-solid, 36 x 109 g jars	1@ 615.44	SB
1411G	AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE Sachets 18.2 g, 60, 1	1@ 544.55	SB
1909L	AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE Sachets 34 g, 30, 1	1@ 511.90	VF
2375B	amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 130 mL cans	1@ 772.99	VF
2654Q	amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 174 mL pouches	1@ 1018.99	VF
2651M	amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 87 mL pouches	1@ 526.99	VF
8592F	amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 30 x 24 g sachets	1@ 526.99	VF
8632H	amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 30 x 25 g sachets	1@ 772.99	VF
8745G	amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 30 x 29 g sachets	1@ 448.51	SB

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name, Form/Strength	Pack and Price	Manufacturer
2380G	amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 400 g	1@ 95.36	SB
8057C	amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 500 g	1@ 337.29	SB
8260R		1@ 222.29	SB
8310J		1@ 666.39	SB
1546J	AMINO ACID FORMULA with VITAMINS and MINERALS without VALINE, LEUCINE and ISOLEUCINE Oral liquid 125 mL, 30, 1	1@ 1030.64	SB
1914R	AMINO ACID FORMULA with VITAMINS and MINERALS without VALINE, LEUCINE and ISOLEUCINE Sachets 34 g, 30, 1	1@ 1021.93	VF
9499Y	amino acid formula with vitamins and minerals without valine, leucine and isoleucine with fat, carbohydrate and trace elements and supplemented with docosahexaenoic acid oral liquid, 36 cans	1@ 625.39	SB
1180D	amino acid synthetic formula oral liquid: powder for, 400 g	1@ 44.34	SB
1192R		1@ 44.34	SB
1521C		1@ 43.77	SB
2250K		1@ 43.77	AB
8574G		1@ 44.34	AB
8575H		1@ 44.34	AB
8754R		1@ 44.34	SB
8755T		1@ 44.34	SB
1545H	amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides oral liquid: powder for, 400 g	1@ 44.65	SB
2900P		1@ 45.18	NT
2928D		1@ 45.18	NT
5466Q		1@ 45.18	SB
5467R		1@ 45.18	SB
2246F	amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids oral liquid: powder for, 400 g	1@ 45.18	SB
2560R		1@ 45.18	SB
9339M		1@ 45.18	AB
9340N		1@ 45.18	AB
8736T	amisulpride 100 mg/mL oral liquid, 60 mL	1@ 71.16	SW
9386B	amylopectin modified long chain oral liquid: powder for, 30 x 60 g sachets	1@ 186.47	VF
10036F	arachidonic acid and docosahexaenoic acid with carbohydrate containing 200 mg arachidonic acid and 100 mg docosahexaenoic acid oral liquid: powder for, 30 x 4 g sachets	1@ 91.10	VF
5482M	arginine with carbohydrate containing 2 g arginine oral liquid: powder for, 30 x 4 g sachets	1@ 191.10	VF
9437Q	arginine with carbohydrate containing 500 mg arginine oral liquid: powder for, 30 x 4 g sachets	1@ 127.40	VF
10093F	arginine with carbohydrate containing 5 g arginine oral liquid: powder for, 30 x 7.6 g sachets	1@ 254.17	VF
9092M	atomoxetine 10 mg capsule, 28	28@ 107.38	LY
9093N	atomoxetine 18 mg capsule, 28	28@ 107.38	LY
9094P	atomoxetine 25 mg capsule, 28	28@ 107.38	LY
9095Q	atomoxetine 40 mg capsule, 28	28@ 107.38	LY
9096R	atomoxetine 60 mg capsule, 28	28@ 107.38	LY
1140B	Bacillus Calmette and Guerin-Connaught strain 660 million colony forming units injection [1 x 81 mg vial] (&) inert substance diluent [1 x 3 mL vial], 1 pack	1@ 151.15	SW
2647H	benzylpenicillin 3 g injection, 1 x 3 g vial	1@ 8.31	CS
3399X		1@ 8.31	CS
1775K	benzylpenicillin 600 mg injection, 1 x 600 mg vial	1@ 4.83	CS
3398W		1@ 4.83	CS
2812B	betamethasone (as valerate) 0.02% (200 microgram/g) cream, 100 g	1@ 8.90	FM, FR
2812B	betamethasone (as valerate) 0.02% (200 microgram/g) cream, 100 g	1@ 10.13	MK
2812B	betamethasone (as valerate) 0.02% (200 microgram/g) cream, 100 g	1@ 12.34	QA
2544X	biperiden hydrochloride 2 mg tablet, 100	100@ 7.23	LM
1260H	bisacodyl 10 mg suppository, 10	1@ 4.84	PP
1260H	bisacodyl 10 mg suppository, 10	1@ 5.34	BY
5303D		1@ 5.34	BY
5303D		1@ 4.84	PP

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name, Form/Strength	Pack and Price	Manufacturer
5307H		1@ 5.34	BY
5307H		1@ 4.84	PP
1258F	bisacodyl 10 mg suppository, 12	1@ 3.97	PP
5304E		1@ 3.97	PP
5308J		1@ 3.97	PP
1443Y	bromocriptine 2.5 mg tablet, 30	30@ 12.50	NV
10015D	budesonide 100 microgram/actuation + eformoterol fumarate dihydrate 3 microgram/actuation inhalation: pressurised, 120 actuations	1@ 26.17	AP
10018G	budesonide 200 microgram/actuation + eformoterol fumarate dihydrate 6 microgram/actuation inhalation: pressurised, 120 actuations	1@ 41.32	AP
10024N	budesonide 50 microgram/actuation + eformoterol fumarate dihydrate 3 microgram/actuation inhalation: pressurised, 120 actuations	1@ 24.02	AP
3116B	CALCIUM Tablet (chewable) 500 mg (as carbonate), 60	60@ 5.62	IA, PP
2422L	CARBAMAZEPINE Tablet 100 mg, 100	100@ 6.04	SZ
2422L	CARBAMAZEPINE Tablet 100 mg, 100	100@ 7.52	NV
5039F		100@ 7.52	NV
5039F		100@ 6.04	SZ
1706T	CARBAMAZEPINE Tablet 200 mg, 100	100@ 11.29	SZ
1706T	CARBAMAZEPINE Tablet 200 mg, 100	100@ 12.77	NV
1724R		100@ 12.77	NV
1724R		100@ 11.29	SZ
1153Q	carbimazole 5 mg tablet, 100	100@ 12.31	LM, PQ
8369L	carbohydrate, fat, vitamins, minerals and trace elements oral liquid: powder for, 400 g	1@ 38.97	SB
10050Y	carbohydrates, fat, vitamins, minerals, trace elements and supplemented with arachidonic acid and docosahexaenoic acid providing 100 kilocalories oral liquid: powder for 30 x 21.5 g sachets	1@ 60.46	VF
10039J	carbohydrates, fat, vitamins, minerals, trace elements and supplemented with arachidonic acid and docosahexaenoic acid providing 200 kilocalories oral liquid: powder for, 30 x 43 g sachets	1@ 116.43	VF
5502N	carbomer-974 0.3% eye gel, 30 x 500 mg unit doses	1@ 9.88	AQ
8514D		1@ 9.88	AQ
5504Q	carbomer-980 0.2% (2 mg/g) eye drops, 30 x 0.6 mL unit doses	1@ 9.89	AQ
8578L		1@ 9.89	AQ
5509Y	carmellose sodium 0.25% (1.5 mg/0.6 mL) eye drops, 24 x 0.6 mL unit doses	1@ 8.50	CX
8823J		1@ 8.50	CX
2338C	carmellose sodium 0.5% (2 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses	1@ 8.29	PP
2338C	carmellose sodium 0.5% (2 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses	1@ 9.88	AG
5506T		1@ 9.88	AG
5506T		1@ 8.29	PP
5561Q	carmellose sodium 0.5% + glycerol 0.9% eye drops, 30 x 0.4 mL unit doses	1@ 9.88	AG
9307W		1@ 9.88	AG
2324H	carmellose sodium 1% (4 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses	1@ 9.88	AG
2324H	carmellose sodium 1% (4 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses	1@ 8.29	PP
5505R		1@ 9.88	AG
5505R		1@ 8.29	PP
5510B	carmellose sodium 1% (6 mg/0.6 mL) eye gel, 28 x 0.6 mL unit doses	1@ 9.22	CX
8824K		1@ 9.22	CX
8315P	CEFEPIME Powder for injection 1 g (as hydrochloride), 1	1@ 5.39	AE, AF, HH, OE, SZ
8316Q	CEFEPIME Powder for injection 2 g (as hydrochloride), 1	1@ 10.26	AE, AF, HH, OE, SZ
1085D	cefotaxime 1 g injection, 1 x 1 g vial	1@ 1.47	SZ
5048Q		1@ 1.47	SZ
1086E	cefotaxime 2 g injection, 1 x 2 g vial	1@ 2.73	SZ
5049R		1@ 2.73	SZ
1784X	ceftriaxone 1 g injection, 1 x 1 g vial	1@ 1.38	AE, HH, PP, SZ
1785Y	ceftriaxone 2 g injection, 1 x 2 g vial	1@ 2.56	AE, AF, HH, SZ
1783W	ceftriaxone 500 mg injection, 1 x 500 mg vial	1@ 0.87	AE, PP
2655R	cephalexin 250 mg capsule, 20	20@ 1.13	AF, CH, CR, EA, GN, GQ, GX, LN, RA, SZ,

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name, Form/Strength	Pack and Price		Manufacturer
2655R	cephalexin 250 mg capsule, 20	20@	5.45	TW, TX
1797N	cephazolin 1 g injection, 5 x 1 g vials	5@	3.73	AS
1799Q		5@	3.73	AE, HH
5479J	cephazolin 2 g injection, 1 x 2 g vial	1@	1.70	AE, HH
9326W		1@	1.70	AF, SZ
1256D	cephazolin 500 mg injection, 5 x 500 mg vials	5@	2.81	AF, SZ
5477G		5@	2.81	AE
1163F	chlorambucil 2 mg tablet, 25	25@	36.84	AE
1585K	chlorthalidone 25 mg tablet, 50	50@	5.58	AS
2967E	cholestyramine 4 g oral liquid: powder for, 50 x 4.7 g sachets	1@	32.76	LM
9249T		1@	32.76	QA
1217C	ciprofloxacin 0.3% eye drops, 5 mL	1@	12.06	QA
1217C	ciprofloxacin 0.3% eye drops, 5 mL	1@	11.03	AQ
5564W		1@	12.06	IQ
5564W		1@	11.03	AQ
5481L	citrulline with carbohydrate containing 1 g citrulline oral liquid: powder for, 30 x 4 g sachets	1@	127.40	IQ
1808E	clonazepam 2.5 mg/mL oral liquid, 10 mL	1@	4.31	VF
5339B		1@	4.31	RO
5342E		1@	4.31	RO
1806C	clonazepam 2 mg tablet, 100	100@	14.25	RO
1806C	clonazepam 2 mg tablet, 100	100@	12.32	AF
1805B	clonazepam 500 microgram tablet, 100	100@	8.25	RO
1805B	clonazepam 500 microgram tablet, 100	100@	6.54	AF
8785J	CODEINE PHOSPHATE with PARACETAMOL Tablet 30 mg-500 mg, 20	20@	0.92	AL, AV, FM, GQ, SZ, TX
8785J	CODEINE PHOSPHATE with PARACETAMOL Tablet 30 mg-500 mg, 20	20@	3.32	SW
8661W	cyclosporin 100 mg/mL oral liquid, 50 mL	1@	353.12	NV
8660T	cyclosporin 100 mg capsule, 30	30@	184.01	NV, SZ
8657P	cyclosporin 10 mg capsule, 60	60@	44.00	NV
8658Q	cyclosporin 25 mg capsule, 30	30@	45.41	NV, SZ
8659R	cyclosporin 50 mg capsule, 30	30@	94.48	NV, SZ
1270W	cypoterone acetate 50 mg tablet, 50	50@	50.30	AF, EA, ER, GN, GX, HX, QA, SY
1270W	cypoterone acetate 50 mg tablet, 50	50@	51.24	BN
9164H	cystine with carbohydrate containing 500 mg cystine oral liquid: powder for, 30 x 4 g sachets	1@	127.40	VF
9319L	dabigatran etexilate 110 mg capsule, 10	10@	15.59	BY
9323Q		10@	15.59	BY
9318K	dabigatran etexilate 75 mg capsule, 10	10@	19.56	BY
9322P		10@	19.56	BY
8959M	DALTEPARIN SODIUM (Low Molecular Weight Heparin Sodium-porcine mucous) Injection 15,000 units (anti-Xa) in 0.6 mL single dose pre-filled syringe, 10	10@	136.11	PF
8960N	DALTEPARIN SODIUM (Low Molecular Weight Heparin Sodium-porcine mucous) Injection 18,000 units (anti-Xa) in 0.72 mL single dose pre-filled syringe, 10	10@	162.39	PF
1229Q	dalteparin sodium 10 000 anti-Xa international units/mL injection, 10 x 1 mL syringes	10@	84.57	PF
8957K		10@	82.88	PF
1296F	dalteparin sodium 12 500 anti-Xa international units/0.5 mL injection, 10 x 0.5 mL syringes	10@	117.43	PF
8958L		10@	114.43	PF
8603T	dalteparin sodium 2500 anti-Xa international units/0.2 mL injection, 10 x 0.2 mL syringes	10@	49.16	PF
8641T		10@	49.16	PF
2816F	dalteparin sodium 5000 anti-Xa international units/0.2 mL injection, 10 x 0.2 mL syringes	10@	51.23	PF
8642W		10@	51.23	PF
8643X	dalteparin sodium 7500 anti-Xa international units/0.75 mL injection, 10 x 0.75 mL syringes	10@	61.96	PF
8956J		10@	61.96	PF
2129C	desmopressin acetate 100 microgram/mL nasal drops, 2.5 mL	1@	30.95	FP
8711L	desmopressin acetate 10 microgram/actuation nasal spray, 60	1@	77.31	FP

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name, Form/Strength	Pack and Price	Manufacturer
	actuators		
8662X	desmopressin acetate 200 microgram tablet, 30	30@ 57.83	FP
5521N	dextran-70 0.1% + hypromellose 0.3% eye drops, 28 x 0.4 mL unit doses	1@ 9.55	AQ
8299T		1@ 9.55	AQ
1302M	diclofenac sodium 100 mg suppository, 20	20@ 9.25	NV
5079H		20@ 9.25	NV
5363G		20@ 9.25	NV
5366K		20@ 9.25	NV
1299J	diclofenac sodium 25 mg tablet: enteric, 50 tablets	50@ 2.65	NV
1299J	diclofenac sodium 25 mg tablet: enteric, 50 tablets	50@ 1.93	AF, CH, EA, GN, QA, SZ, TW, TX
5076E		50@ 1.93	AF, CH, EA, GN, QA, SZ, TW, TX
5076E		50@ 2.65	NV
5361E		50@ 1.93	AF, CH, EA, GN, QA, SZ, TW, TX
5361E		50@ 2.65	NV
5364H		50@ 1.93	AF, CH, EA, GN, QA, SZ, TW, TX
5364H		50@ 2.65	NV
3164M	digoxin 50 microgram/mL oral liquid, 60 mL	1@ 17.35	QA
10040K	docosahexaenoic acid with carbohydrate containing 200 mg docosahexaenoic acid oral liquid: powder for, 30 x 4g sachets	1@ 91.10	VF
2703G	doxycycline 100 mg capsule: modified release, 7 capsules	7@ 3.09	YN
2703G	doxycycline 100 mg capsule: modified release, 7 capsules	7@ 1.93	YT
2702F	doxycycline 100 mg tablet, 7	7@ 1.09	AF, GN, QA
2714W		7@ 1.09	AF, EA, GN, QA
9107H		7@ 1.09	CH, GX, HX, TW
9108J		7@ 1.09	CH, HX, TW
5435C	enoxaparin sodium 100 mg/mL injection, 10 x 1 mL syringes	10@ 102.33	SW
8558K	enoxaparin sodium 20 mg/0.2 mL injection, 10 x 0.2 mL syringes	10@ 49.16	SW
8716R		10@ 49.16	SW
9195Y	enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL ampoules	10@ 51.23	SW
9196B		10@ 51.23	SW
8510X	enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL syringes	10@ 51.23	SW
8639Q		10@ 51.23	SW
8640R	enoxaparin sodium 60 mg/0.6 mL injection, 10 x 0.6 mL syringes	10@ 73.26	SW
5434B	enoxaparin sodium 80 mg/0.8 mL injection, 10 x 0.8 mL syringes	10@ 84.28	SW
8367J	entacapone 200 mg tablet, 100	100@ 137.70	NV
8397Y	eprosartan 400 mg tablet, 28	28@ 8.86	GO
8951D		28@ 8.86	GO
8683B	eptifibatide 20 mg/10 mL injection, 1 x 10 mL vial	1@ 128.06	MK
8684C	eptifibatide 75 mg/100 mL injection, 1 x 100 mL vial	1@ 337.98	MK
1397M	erythromycin (as lactobionate) 1 g injection, 1 x 1 g vial	1@ 38.01	LM
5088T		1@ 38.01	LM
9329B	essential amino acids formula oral liquid: powder for, 2 x 200 g cans	1@ 199.02	SB
2027Q	essential amino acids formula with minerals and vitamin C oral liquid: powder for, 400 g	1@ 125.55	SB
9385Y	essential amino acids formula with vitamins and minerals oral liquid: powder for, 50 x 12.5 g sachets	1@ 377.52	VF
1954W	etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack	1@ 883.97	PF
3445H		1@ 883.97	PF
3448L		1@ 883.97	PF
8637N		1@ 883.97	PF
8638P		1@ 883.97	PF
8778B		1@ 883.97	PF
8779C		1@ 883.97	PF
9035M		1@ 883.97	PF
9036N		1@ 883.97	PF
9037P		1@ 883.97	PF
9429G		1@ 883.97	PF
8748K	ethacrynic acid 25 mg tablet, 100	100@ 95.44	FK
9352F	everolimus 1 mg tablet, 60	60@ 1031.17	NV
8842J	everolimus 750 microgram tablet, 60	60@ 786.10	NV

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name, Form/Strength	Pack and Price	Manufacturer
5411T	FENTANYL Lozenge 1200 micrograms (as citrate), 30	30@ 285.15	OA
5412W	FENTANYL Lozenge 1600 micrograms (as citrate), 30	30@ 285.15	OA
5407N	FENTANYL Lozenge 200 micrograms (as citrate), 30	30@ 285.15	OA
5408P	FENTANYL Lozenge 400 micrograms (as citrate), 30	30@ 285.15	OA
5409Q	FENTANYL Lozenge 600 micrograms (as citrate), 30	30@ 285.15	OA
5410R	FENTANYL Lozenge 800 micrograms (as citrate), 30	30@ 285.15	OA
1473M	fluconazole 100 mg/50 mL injection, 1 x 50 mL vial	1@ 2.25	HX, SZ
1474N	fluconazole 200 mg/100 mL injection, 1 x 100 mL vial	1@ 4.24	AF, HX, SZ
1433K	fludrocortisone acetate 100 microgram tablet, 100	100@ 20.04	QA
2958Q	folic acid 500 microgram tablet, 100	100@ 2.46	AF, PP
1437P	folic acid 5 mg tablet, 100	100@ 3.80	AF
8812T	folinic acid 100 mg/10 mL injection, 1 x 10 mL vial	1@ 4.80	SZ
9041W	folinic acid 300 mg/30 mL injection, 1 x 30 mL vial	1@ 14.00	HH, SZ
8740B	folinic acid 50 mg/5 mL injection, 1 x 5 mL vial	1@ 5.18	HH
8713N	follitropin alfa 300 international units / 0.5 mL (21.84 microgram/0.5 mL) injection, 1 x 0.5 mL cartridge	1@ 162.36	SG
8714P	follitropin alfa 450 international units / 0.75 mL (32.76 microgram/0.75 mL) injection, 1 x 0.75 mL cartridge	1@ 243.55	SG
8715Q	follitropin alfa 900 international units / 1.5 mL (65.52 microgram/1.5 mL) injection, 1 x 1.5 mL cartridge	1@ 487.09	SG
8565T	follitropin beta 300 international units/0.36 mL injection, 1 x 0.36 mL cartridge	1@ 167.73	MK
8566W	follitropin beta 600 international units/0.72 mL injection, 1 x 0.72 mL cartridge	1@ 327.32	MK
8871X	follitropin beta 900 international units/1.08 mL injection, 1 x 1.08 mL cartridge	1@ 486.58	MK
8775W	FONDAPARINUX SODIUM Injection 2.5 mg in 0.5 mL single dose pre-filled syringe, 2	2@ 37.05	AS
1810G	frusemide 20 mg tablet, 50	50@ 0.77	FM
1810G	frusemide 20 mg tablet, 50	50@ 1.61	SW
8444K	gelatin-succinylated 20 g/500 mL injection, 1 x 500 mL bag	1@ 13.11	BR
2245E	glucose 5% (50 g/1000 mL) injection, 1 x 1000 mL bag	1@ 1.84	BX
5106R		1@ 1.84	BX
3106L	glucose and ketone indicator urine strip: diagnostic, 50 diagnostic strips	1@ 5.44	RD
3107M		1@ 5.50	BN
9254C		1@ 5.44	RD
9255D		1@ 5.50	BN
10139P	glucose indicator blood strip: diagnostic, 50	1@ 23.38	WI
10147C		1@ 23.38	WI
10215P		1@ 23.38	IF
10216Q		1@ 23.38	IF
10217R		1@ 23.38	IF
10223C		1@ 23.38	IF
2263D		1@ 23.38	MS
2673Q		1@ 23.38	JJ
2697Y		1@ 23.38	JJ
2860M		1@ 23.38	NA
2890D		1@ 23.38	NA
2914J		1@ 19.74	NA
3406G		1@ 23.38	PB
3407H		1@ 23.38	PB
3441D		1@ 23.38	JJ
3442E		1@ 23.38	JJ
5043K		1@ 23.38	RD
5053Y		1@ 23.38	RD
8739Y		1@ 23.38	RD
8749L		1@ 23.38	OZ
8759B		1@ 23.38	PB
8795X		1@ 23.38	PX
9263M		1@ 23.38	OZ
9267R		1@ 23.38	MS
9274D		1@ 23.38	RD
9276F		1@ 23.38	NA
9277G		1@ 23.38	NA
9278H		1@ 23.38	PB

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name, Form/Strength	Pack and Price	Manufacturer
9279J		1@ 19.74	NA
9281L		1@ 23.38	PX
9297H		1@ 23.38	QB
9298J		1@ 23.38	QB
9471L		1@ 23.38	EH
9472M		1@ 23.38	EH
9485F		1@ 23.38	OI
9486G		1@ 23.38	OI
8806L	glucose indicator blood strip: diagnostic, 51 diagnostic strips	1@ 23.38	RD
9275E		1@ 23.38	RD
3104J	glucose indicator urine strip: diagnostic, 50 diagnostic strips	1@ 6.70	BN
9253B		1@ 6.70	BN
2556M	glycerol 1.4 g suppository, 12	1@ 4.93	PP
5312N		1@ 4.93	PP
5315R		1@ 4.93	PP
2557N	glycerol 2.8 g suppository, 12	1@ 5.13	PP
5313P		1@ 5.13	PP
5316T		1@ 5.13	PP
2555L	glycerol 700 mg suppository, 12	1@ 4.78	PP
5311M		1@ 4.78	PP
5314Q		1@ 4.78	PP
10195N	glycine with carbohydrate containing 500 mg of glycine oral liquid: powder for, 30 x 4 g sachets	1@ 127.40	VF
2712R	glycomacropeptide and essential amino acids oral liquid, 12 x 500 mL bottles	1@ 105.31	QH
2696X	glycomacropeptide and essential amino acids with vitamins and minerals bar, 7 x 54 g	1@ 61.43	QH
2644E	glycomacropeptide and essential amino acids with vitamins and minerals bar, 7 x 81 g	1@ 92.15	QH
2685H	glycomacropeptide and essential amino acids with vitamins and minerals oral liquid: powder for, 28 x 49 g sachets	1@ 368.34	QH
8728J	granisetron 2 mg tablet, 1	1@ 11.49	RO
1076P	heparin sodium 35 000 international units/35 mL injection, 1 x 35 mL vial	1@ 31.15	HH
2652N	high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (3:1 ratio long chain fat to carbohydrate plus protein) oral liquid: powder for, 300 g	1@ 42.96	SB
10185C	high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (4:1 ratio long chain fat to carbohydrate plus protein) oral liquid, 32 x 200 mL cartons	1@ 196.11	SB
9446E	high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (4:1 ratio long chain fat to carbohydrate plus protein) oral liquid: powder for, 300 g	1@ 42.96	SB
1640H	hydralazine hydrochloride 25 mg tablet, 100	100@ 5.44	AF
1639G	hydralazine hydrochloride 50 mg tablet, 100	100@ 6.30	AF
1486F	hydrochlorothiazide 50 mg + amiloride hydrochloride 5 mg tablet, 50	50@ 3.54	AS
1501B	hydrocortisone (as sodium succinate) 100 mg injection [1 x 100 mg vial] (&) inert substance diluent [1 x 2 mL vial], 1 pack	1@ 5.64	PF
1510L		1@ 5.64	PF
5118J		1@ 5.64	PF
1511M	hydrocortisone (as sodium succinate) 250 mg injection [1 x 250 mg vial] (&) inert substance diluent [1 x 2 mL vial], 1 pack	1@ 9.64	PF
5119K		1@ 9.64	PF
1502C	hydrocortisone acetate 10% (100 mg/g) enema, 21.1 g	1@ 17.01	HM
9487H	HYDROXYETHYL STARCH 130/0.4 I.V. infusion 30 g per 500 mL, 500 mL, 1	1@ 13.11	PK
5317W	hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules	5@ 17.02	BY
5318X		5@ 17.02	BY
3190X	ibuprofen 400 mg tablet, 30	30@ 2.77	GO
5123P		30@ 2.77	GO
5368M		30@ 2.77	GO
5370P		30@ 2.77	GO
2448W	idarubicin hydrochloride 10 mg capsule, 1	1@ 162.69	PF
2446R	idarubicin hydrochloride 5 mg capsule, 1	1@ 87.06	PF
2757D	indomethacin 100 mg suppository, 20	20@ 8.04	AS

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name, Form/Strength	Pack and Price	Manufacturer
5128X		20@ 8.04	AS
5378C		20@ 8.04	AS
5380E		20@ 8.04	AS
2454E	indomethacin 25 mg capsule, 50	50@ 5.54	AS
2454E	indomethacin 25 mg capsule, 50	50@ 3.22	AF
5126T		50@ 5.54	AS
5126T		50@ 3.22	AF
5377B		50@ 5.54	AS
5377B		50@ 3.22	AF
5379D		50@ 3.22	AF
5379D		50@ 5.54	AS
8571D	insulin aspart 100 international units/mL injection, 1 x 10 mL vial	1@ 30.57	NO
8435Y	insulin aspart 100 international units/mL injection, 5 x 3 mL cartridges	1@ 51.56	NF, NO
8609D	insulin aspart 30 international units/mL + insulin aspart protamine 70 international units/mL injection, 5 x 3 mL syringes	1@ 51.56	NF, NO
9040T	insulin detemir 100 international units/mL injection, 5 x 3 mL cartridges	1@ 85.26	NF, NO
9039R	insulin glargine 100 international units/mL injection, 5 x 3 mL cartridges	1@ 85.26	AV, SW
9224L	insulin glulisine 100 international units/mL injection, 1 x 10 mL vial	1@ 30.57	SW
1921D	insulin glulisine 100 international units/mL injection, 5 x 3 mL cartridges	1@ 51.56	AV, SW
1711C	insulin isophane bovine 100 international units/mL injection, 1 x 10 mL vial	1@ 78.86	AS
1533Q	insulin isophane human 100 international units/mL injection, 1 x 10 mL vial	1@ 25.48	LY, NO
1761Q	insulin isophane human 100 international units/mL injection, 5 x 3 mL cartridges	1@ 43.58	LY, NI, NO
1763T	insulin isophane human 70 international units/mL + insulin neutral human 30 international units/mL injection, 5 x 3 mL cartridges	1@ 43.58	LY, NI, NO
8084L	insulin lispro 100 international units/mL injection, 1 x 10 mL vial	1@ 30.57	LY
8212F	insulin lispro 100 international units/mL injection, 5 x 3 mL cartridges	1@ 51.56	KP, LY
8390N	insulin lispro 25 international units/mL + insulin lispro protamine 75 international units/mL injection, 5 x 3 mL cartridges	1@ 51.56	KP, LY
8874C	insulin lispro 50 international units/mL + insulin lispro protamine 50 international units/mL injection, 5 x 3 mL cartridges	1@ 51.56	KP, LY
1713E	insulin neutral bovine 100 international units/mL injection, 1 x 10 mL vial	1@ 78.86	AS
1531N	insulin neutral human 100 international units/mL injection, 1 x 10 mL vial	1@ 25.48	LY, NO
1762R	insulin neutral human 100 international units/mL injection, 5 x 3 mL cartridges	1@ 43.58	LY, NO
1426C	insulin neutral human 30 international units/mL + insulin isophane human 70 international units/mL injection, 1 x 10 mL vial	1@ 25.48	LY
2062M	insulin neutral human 50 international units/mL + insulin isophane human 50 international units/mL injection, 5 x 3 mL cartridges	1@ 43.58	NO
8180M	interferon alfa-2a 3 million international units/0.5 mL injection, 1 x 0.5 mL syringe	1@ 33.32	RO
8181N		1@ 33.32	RO
8182P	interferon alfa-2a 4.5 million international units/0.5 mL injection, 1 x 0.5 mL syringe	1@ 51.66	RO
8551C		1@ 51.66	RO
8183Q	interferon alfa-2a 6 million international units/0.5 mL injection, 1 x 0.5 mL syringe	1@ 67.66	RO
8552D		1@ 67.66	RO
8184R	interferon alfa-2a 9 million international units/0.5 mL injection, 1 x 0.5 mL syringe	1@ 99.94	RO
8553E		1@ 99.94	RO
8348J	interferon alfa-2b 18 million international units/1.2 mL injection, 1 x 1.2 mL cartridge	1@ 199.87	MK
8572E		1@ 199.87	MK
8476D	interferon alfa-2b 30 million international units/1.2 mL injection, 1 x 1.2 mL cartridge	1@ 333.11	MK
8671J	ipratropium bromide 20 microgram/actuation inhalation: pressurised, 200 actuations	1@ 13.71	BY
1542E	ipratropium bromide 250 microgram/mL inhalation: solution, 30 x 1 mL ampoules	1@ 10.76	AF, QA, TX
1542E	ipratropium bromide 250 microgram/mL inhalation: solution, 30 x 1 mL	1@ 11.02	BY

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name, Form/Strength	Pack and Price	Manufacturer
8238N	ampoules ipratropium bromide 500 microgram/mL inhalation: solution, 30 x 1 mL	1@ 12.72	AF, QA, TX
8238N	ampoules ipratropium bromide 500 microgram/mL inhalation: solution, 30 x 1 mL	1@ 12.96	BY
10104T	iron (as ferric carboxymaltose) 500 mg/10 mL injection, 1 x 10 mL vial	1@ 155.23	VL
9436P	isoleucine with carbohydrate containing 1 g isoleucine oral liquid: powder for, 30 x 4 g sachets	1@ 140.14	VF
9134R	isoleucine with carbohydrate containing 50 mg isoleucine oral liquid: powder for, 30 x 4 g sachets	1@ 127.40	VF
2588F	isosorbide dinitrate 5 mg tablet: sublingual, 100	100@ 4.07	QA
2868Y	ivermectin 3 mg tablet, 4	4@ 23.89	MK
1588N	ketoprofen 100 mg suppository, 20	20@ 9.44	SW
5139L		20@ 9.44	SW
2286H	lactate sodium 0.322% (3.22 g/1000 mL) + sodium chloride 0.6% (6 g/1000 mL) + potassium chloride 0.04% (400 mg/1000 mL) + calcium chloride dihydrate 0.027% (270 mg/1000 mL) injection, 1 x 1000 mL bag	1@ 1.58	BX
5387M	LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1	1@ 3.94	QA
5387M	LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1	1@ 4.83	AF, FM
5388N		1@ 4.83	AF, FM
5388N		1@ 3.94	QA
9148L	lapatinib 250 mg tablet, 70	70@ 1690.52	GK
8798C	levodopa 100 mg + carbidopa anhydrous 25 mg + entacapone 200 mg tablet, 100	100@ 167.75	NV
9345W	levodopa 125 mg + carbidopa anhydrous 31.25 mg + entacapone 200 mg tablet, 100	100@ 173.77	NV
8799D	levodopa 150 mg + carbidopa anhydrous 37.5 mg + entacapone 200 mg tablet, 100	100@ 182.77	NV
9292C	levodopa 200 mg + carbidopa anhydrous 50 mg + entacapone 200 mg tablet, 100	100@ 196.60	NV
8970D	levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL gel: intestinal, 7 x 100 mL bags	7@ 1459.49	VE
8797B	levodopa 50 mg + carbidopa anhydrous 12.5 mg + entacapone 200 mg tablet, 100	100@ 152.73	NV
9344T	levodopa 75 mg + carbidopa anhydrous 18.75 mg + entacapone 200 mg tablet, 100	100@ 159.35	NV
8290H	lithium carbonate 450 mg tablet: modified release, 100 tablets	100@ 13.94	AS
8203R	losartan potassium 50 mg tablet, 30	30@ 8.99	AF
10112F	macrogol-3350 13.12 g/25 mL + sodium chloride 350.7 mg/25 mL + potassium chloride 46.6 mg/25 mL (0.63 mmol/25 mL potassium) + sodium bicarbonate 178.5 mg/25 mL oral liquid, 500 mL	1@ 7.88	NE
10126Y		1@ 7.88	NE
10127B		1@ 7.88	NE
5389P	macrogol-3350 13.12 g + sodium chloride 350.7 mg + potassium chloride 46.6 mg (0.63 mmol potassium) + sodium bicarbonate 178.5 mg solution, 30 sachets	1@ 11.81	AE, GN, HM, NE, QA, TX
5390Q		1@ 11.81	AE, GN, HM, NE, QA, TX
2351R	macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets	1@ 11.81	ON
2353W		1@ 11.81	ON
5426N	macrogol-3350 1 g/g oral liquid: powder for, 510 g	1@ 11.81	KY
5427P		1@ 11.81	KY
1598D	mercaptopurine 50 mg tablet, 25	25@ 65.09	AS
8753Q	mesalazine 1 g/100 mL enema, 7 x 100 mL	1@ 82.45	FP
8768L	mesalazine 1 g/application enema, 14 applications	1@ 82.45	OA
3413P	mesalazine 1 g tablet: modified release, 60 tablets	60@ 162.13	FP
8616L	mesalazine 2 g/60 mL enema, 7 x 60 mL	1@ 82.45	OA
8617M	mesalazine 4 g/60 mL enema, 7 x 60 mL	1@ 109.87	OA
8598M	mesalazine 500 mg granules, 100 x 500 mg sachets	100@ 145.51	OA
8731M	mesalazine 500 mg tablet: enteric, 100 tablets	100@ 145.51	OA
2214M	mesalazine 500 mg tablet: modified release, 100 tablets	100@ 145.51	FP
1818Q	METHOTREXATE Injection 50 mg in 2 mL, 1	1@ 2.59	GN, YN
5423K	methylnaltrexone bromide 12 mg/0.6 mL injection, 1 x 0.6 mL vial	1@ 41.39	LM
2277W	metronidazole 500 mg/100 mL (0.5%) injection, 5 x 100 mL bags	5@ 5.59	AE
2298Y		5@ 5.59	AE

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name, Form/Strength	Pack and Price		Manufacturer
8282X	milk powder lactose free formula oral liquid: powder for, 900 g	1@	21.29	AS
8283Y		1@	21.29	AS
2975N	milk powder lactose free formula predigested oral liquid: powder for, 900 g	1@	17.80	NU
2989H		1@	17.80	NU
2357C	milk powder lactose modified predigested oral liquid: powder for, 900 g	1@	22.13	SJ
2358D		1@	22.13	SJ
3092R	milk powder synthetic low calcium oral liquid: powder for, 400 g	1@	46.87	SB
8630F	milk protein and fat formula with vitamins and minerals carbohydrate free oral liquid: powder for, 225 g	1@	26.75	SB
8816B	modafinil 100 mg tablet, 60	60@	170.28	CS
1836P	mycophenolate Capsule 250 mg, 50	50@	51.75	AF
8649F	mycophenolate mofetil 250 mg capsule, 100	100@	103.50	CR, RO, SZ, TX
8650G	mycophenolate mofetil 500 mg tablet, 50	50@	103.49	AF, CR, RO, SZ, TX
2192J	naloxone hydrochloride 400 microgram/mL injection, 1 x 1 mL syringe	1@	19.68	UC
2196N		1@	19.68	UC
1674D	naproxen 250 mg tablet, 50	50@	4.58	RO
1674D	naproxen 250 mg tablet, 50	50@	3.46	AF
5176K		50@	3.46	AF
5176K		50@	4.58	RO
5345H		50@	3.46	AF
5345H		50@	4.58	RO
5349M		50@	3.46	AF
5349M		50@	4.58	RO
8298R	naratriptan 2.5 mg tablet, 2	2@	11.13	AS
9734H		2@	11.13	AS
9316H	nebivolol 1.25 mg tablet, 28	28@	22.10	FK
2732T	nitrazepam 5 mg tablet, 25	25@	1.59	AF
2732T	nitrazepam 5 mg tablet, 25	25@	2.83	IA
5359C		25@	2.83	IA
5359C		25@	1.59	AF
5360D		25@	2.83	IA
5360D		25@	1.59	AF
1698J	nystatin 100 000 international units/g cream, 15 g	1@	6.07	FM
5567B	ofloxacin 0.3% (3 mg/mL) eye drops, 5 mL	1@	14.44	AG
8383F		1@	14.44	AG
9294E	olanzapine 210 mg injection: modified release [1 x 210 mg vial] (&) inert substance diluent [1 x 3 mL vial], 1 pack	1@	246.68	LY
9295F	olanzapine 300 mg injection: modified release [1 x 300 mg vial] (&) inert substance diluent [1 x 3 mL vial], 1 pack	1@	401.42	LY
3134Y	oxazepam 15 mg tablet, 25	25@	1.24	AF
3134Y	oxazepam 15 mg tablet, 25	25@	3.92	QA
5371Q		25@	3.92	QA
5371Q		25@	1.24	AF
5373T		25@	1.24	AF
5373T		25@	3.92	QA
3135B	oxazepam 30 mg tablet, 25	25@	1.24	AF, FM, TX
3135B	oxazepam 30 mg tablet, 25	25@	3.92	QA
5372R		25@	1.24	AF, FM, TX
5372R		25@	3.92	QA
5374W		25@	1.24	AF, FM, TX
5374W		25@	3.92	QA
8588B	oxcarbazepine 60 mg/mL oral liquid, 250 mL	1@	65.85	NV
8461H	pamidronate disodium 15 mg/5 mL injection, 1 x 5 mL vial	1@	20.30	HH
8462J	pamidronate disodium 30 mg/10 mL injection, 1 x 10 mL vial	1@	40.60	HH
8020D	pancreatic extract 10 000 international units capsule: modified release, 100 capsules	100@	35.45	GO
9226N		100@	35.45	GO
8021E	pancreatic extract 25 000 international units capsule: modified release, 100 capsules	100@	70.66	GO
9227P		100@	70.66	GO
9412J	pancreatic extract 40 000 international units capsule: modified release, 100 capsules	100@	111.77	GO
9413K		100@	111.77	GO
5453B	pancreatic extract 5000 international units/100 mg granules: enteric-	1@	45.12	GO

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name, Form/Strength	Pack and Price	Manufacturer
	coated, 20 g		
5454C		1@ 45.12	GO
8366H	pancrelipase 25 000 units capsule, 100	100@ 65.74	TM
9229R		100@ 65.74	TM
5319Y	paracetamol 500 mg suppository, 24	1@ 19.51	GC
5320B		1@ 19.51	GC
5224Y	paracetamol 500 mg tablet, 100	100@ 1.90	AF, FM, GN, GQ, SW, SZ, TX
8784H		100@ 1.90	AF, FM, GN, GQ, SW, SZ, TX
5343F	paracetamol 665 mg tablet: modified release, 96 tablets	96@ 5.11	GC
5343F	paracetamol 665 mg tablet: modified release, 96 tablets	96@ 4.29	CR
5344G		96@ 4.29	CR
5344G		96@ 5.11	GC
8814X		96@ 5.11	GC
8814X		96@ 4.29	CR
2167C	paraffin + retinyl palmitate 138 microgram/g (equivalent to 250 units/g vitamin A) eye ointment, 5 g	1@ 7.41	AE
2202X		1@ 7.41	AE
2222Y		1@ 7.41	AE
1754H	paraffin 1 g/g eye ointment, 3.5 g	1@ 7.41	IQ
1754H	paraffin 1 g/g eye ointment, 3.5 g	1@ 8.68	AQ
5523Q		1@ 8.68	AQ
5523Q		1@ 7.41	IQ
9217D		1@ 7.41	IQ
9217D		1@ 8.68	AQ
10157N	perampanel 2 mg tablet, 7	7@ 22.94	EI
1166J	phenoxybenzamine hydrochloride 10 mg capsule, 30	1@ 66.16	GH
5024K	phenoxymethylpenicillin 125 mg/5 mL oral liquid: powder for, 100 mL	1@ 3.88	AE
8976K		1@ 3.88	AE
5012T	phenoxymethylpenicillin 150 mg/5 mL oral liquid, 100 mL	1@ 8.54	QA
5012T	phenoxymethylpenicillin 150 mg/5 mL oral liquid, 100 mL	1@ 7.59	FM
9143F		1@ 8.54	QA
9143F		1@ 7.59	FM
5029Q	phenoxymethylpenicillin 250 mg/5 mL oral liquid: powder for, 100 mL	1@ 5.16	AE
8977L		1@ 5.16	AE
1703P	phenoxymethylpenicillin 250 mg tablet, 25	25@ 2.45	QA
1787C		25@ 2.45	QA
3360W		25@ 2.45	QA
3028J	phenoxymethylpenicillin 500 mg tablet, 25	25@ 3.62	QA
3361X		25@ 3.62	QA
9384X	phenylalanine with carbohydrate containing 50 mg phenylalanine oral liquid: powder for, 30 x 4 g sachets	1@ 127.40	VF
5532E	polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses	1@ 13.83	AQ
9170P		1@ 13.83	AQ
9475Q	polylactic acid 150 mg injection, 1 x 150 mg vial	1@ 220.02	GA
9476R		1@ 220.02	GA
2642C	potassium chloride 600 mg (8 mmol potassium) tablet: modified release, 100 tablets	100@ 4.70	NV
2642C	potassium chloride 600 mg (8 mmol potassium) tablet: modified release, 100 tablets	100@ 3.23	NM
1920C	prednisolone (as sodium phosphate) 20 mg/100 mL enema, 7 x 100 mL	7@ 51.23	QA
2554K	prednisolone (as sodium phosphate) 5 mg suppository, 10	1@ 11.76	QA
1948M	promethazine hydrochloride 50 mg/2 mL injection, 5 x 2 mL ampoules	5@ 11.91	HH
3374N		5@ 11.91	HH
1953T	propantheline bromide 15 mg tablet, 100	100@ 10.02	QA
1955X	propylthiouracil 50 mg tablet, 100	100@ 21.61	PL
2676W	protein hydrolysate formula with medium chain triglycerides oral liquid: powder for, 400 g	1@ 20.69	NT
8259Q	protein hydrolysate formula with medium chain triglycerides oral liquid: powder for, 450 g	1@ 12.93	NU
2608G	pyridostigmine bromide 180 mg tablet: modified release, 50 tablets	50@ 71.40	IA
2724J	PYRIDOSTIGMINE BROMIDE Tablet 10 mg, 50	50@ 8.29	IA
8162N	ranitidine 150 mg/10 mL oral liquid, 300 mL	1@ 9.05	AS

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name, Form/Strength	Pack and Price		Manufacturer
1937Y	ranitidine 150 mg tablet: effervescent, 30	30@	2.68	AS
8790P	risperidone 1 mg tablet: orally disintegrating, 28	28@	7.68	JC
8792R		28@	7.68	JC
8780D	risperidone 25 mg injection: modified release [1 x 25 mg vial] (&) inert substance diluent [1 x 2 mL syringe], 1 pack	1@	135.34	JC
8794W	risperidone 2 mg tablet: orally disintegrating, 28	28@	15.42	JC
9080X		28@	15.42	JC
8781E	risperidone 37.5 mg injection: modified release [1 x 37.5 mg vial] (&) inert substance diluent [1 x 2 mL syringe], 1 pack	1@	173.51	JC
9075P	risperidone 3 mg tablet: orally disintegrating, 28	28@	22.17	JC
9076Q	risperidone 4 mg tablet: orally disintegrating, 28	28@	29.22	JC
1842Y	risperidone 500 microgram tablet, 20	20@	2.29	JC, TX
1846E		20@	2.29	JC, TX
8788M	risperidone 500 microgram tablet: orally disintegrating, 28	28@	3.83	JC
8870W		28@	3.83	JC
8782F	risperidone 50 mg injection: modified release [1 x 50 mg vial] (&) inert substance diluent [1 x 2 mL syringe], 1 pack	1@	211.28	JC
9313E	rizatriptan 10 mg wafer, 2	2@	9.35	MK
8288F	salbutamol 100 microgram/actuation inhalation: pressurised, 200	1@	3.69	AL, TX
8288F	salbutamol 100 microgram/actuation inhalation: pressurised, 200	1@	4.86	GK
2000G	salbutamol 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules	1@	4.60	AF, CR, GN, GX, QA, SZ, TX, UA
2000G	salbutamol 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules	1@	5.20	GK
10143W	salbutamol 200 microgram inhalation: powder for, 128 capsules	128@	6.18	GK
1103C	salbutamol 2 mg/5 mL oral liquid, 150 mL	1@	7.89	GK
2001H	salbutamol 5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules	1@	4.84	AF, CR, GN, GX, QA, SZ, TX, UA
2001H	salbutamol 5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules	1@	5.42	GK
8354Q	salbutamol Oral pressurised inhalation in breath actuated device 100 micrograms (base) per dose (200 doses), CFC-free formulation, 1	1@	16.09	IA
2997R	salcatonin 100 international units/mL injection, 5 x 1 mL ampoules	5@	51.57	NV
10086W	sapropterin dihydrochloride 100 mg tablet: soluble, 30 tablets	30@	883.33	SG
10087X		30@	883.33	SG
2281C	sodium chloride 0.18% (1.8 g/1000 mL) + glucose 4% (40 g/1000 mL) injection, 1 x 1000 mL bag	1@	3.42	BX
5214K		1@	3.42	BX
2264E	sodium chloride 0.9% (9 g/1000 mL) injection, 1 x 1000 mL bag	1@	1.69	BX
5212H		1@	1.69	BX
3199J	sodium gluconate 5.02 g/1000 mL + sodium chloride 5.26 g/1000 mL + potassium chloride 370 mg/1000 mL + magnesium chloride 300 mg/1000 mL + sodium acetate trihydrate 3.68 g/1000 mL + glucose 5% (50 g/1000 mL) injection, 1 x 1000 mL bag	1@	7.77	BX
10226F	sorafenib 200 mg tablet, 60	60@	3225.33	BN
10242C		60@	3225.33	BN
9380Q		60@	3225.33	BN
2091C	sorbitol 3.125 g/5 mL + citrate sodium dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 12 x 5 mL	1@	12.93	AE, JT
5331N		1@	12.93	AE, JT
5332P		1@	12.93	AE, JT
5545W	soy lecithin 1% (10 mg/mL) + tocopherols 0.002% (20 microgram/mL) + vitamin A palmitate 0.025% (250 microgram/mL) eye spray, 100 actuations	1@	14.82	RB
9448G		1@	14.82	RB
8577K	soy protein and fat formula with vitamins and minerals carbohydrate free oral liquid, 1 x 384 mL can	1@	5.53	AB
2093E	sulfasalazine 500 mg tablet, 100	100@	21.93	PF
9208P		100@	21.93	PF
2096H	SULFASALAZINE Tablet 500 mg (enteric coated), 100	100@	25.16	PF
2096H	SULFASALAZINE Tablet 500 mg (enteric coated), 100	100@	23.92	FZ
9209Q		100@	23.92	FZ
9209Q		100@	25.16	PF
8885P	SUMATRIPTAN Tablet (fast disintegrating) 50 mg (as succinate), 2	2@	5.00	AS
8144P	SUMATRIPTAN Tablet 50 mg (as succinate), 2	2@	3.98	AF, AL, AS, CH, QA, SZ, TW, TX
8144P	SUMATRIPTAN Tablet 50 mg (as succinate), 2	2@	5.00	LN

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name, Form/Strength	Pack and Price	Manufacturer
1880Y	tamoxifen 20 mg tablet, 30	30@ 13.96	AP
2088X	temazepam 10 mg tablet, 25	25@ 0.93	AF, FM, TX
2088X	temazepam 10 mg tablet, 25	25@ 4.93	QA
5375X		25@ 0.93	AF, FM, TX
5375X		25@ 4.93	QA
5376Y		25@ 4.93	QA
5376Y		25@ 0.93	AF, FM, TX
8821G	temozolomide 100 mg capsule, 5	5@ 346.05	AF, EA, GN, MK, ON, QA
9361Q	temozolomide 140 mg capsule, 5	5@ 468.10	AF, EA, GN, MK, ON, QA
10062N	temozolomide 180 mg capsule, 5	5@ 586.59	GN, MK, ON
8820F	temozolomide 20 mg capsule, 5	5@ 83.67	AF, EA, GN, MK, ON, QA
8819E	temozolomide 5 mg capsule, 5	5@ 29.06	AF, EA, GN, MK, ON, QA
9160D	terbinafine hydrochloride 1% cream, 15 g	1@ 15.47	NC
2817G	terbutaline sulfate 500 microgram/actuation inhalation: powder for, 100 actuations	1@ 5.72	AP
2832C	tetracosactrin 1 mg/mL injection: modified release, 1 x 1 mL ampoule	1@ 12.97	NV
8222R	tiagabine 10 mg tablet, 50	50@ 66.21	OA
8223T	tiagabine 15 mg tablet, 50	50@ 95.24	OA
8221Q	tiagabine 5 mg tablet, 50	50@ 33.10	OA
10113G	ticarcillin 3 g + clavulanic acid 100 mg injection, 1 x 3.1 g vial	1@ 15.70	AS
10125X		1@ 15.70	AS
1356J	tobramycin 80 mg/2 mL injection, 5 x 2 mL vials	5@ 29.30	HH
8872Y	tobramycin Injection 80 mg (base) in 2 mL (without preservative), 5	5@ 29.30	PF
2117K	triamcinolone acetonide 0.02% (200 microgram/g) cream, 100 g	1@ 3.99	FM
2117K	triamcinolone acetonide 0.02% (200 microgram/g) cream, 100 g	1@ 5.88	QA
2118L	triamcinolone acetonide 0.02% (200 microgram/g) ointment, 100 g	1@ 5.88	QA
2118L	triamcinolone acetonide 0.02% (200 microgram/g) ointment, 100 g	1@ 3.99	FM
10037G	triglycerides long chain oral liquid, 18 x 250 mL cartons	1@ 146.70	VF
9308X	triglycerides long chain with glucose polymer oral liquid, 18 x 250 mL cans	1@ 55.56	VF
10189G	triglycerides long chain with glucose polymer oral liquid, 27 x 200 mL cartons	1@ 92.71	SB
9309Y	triglycerides long chain with glucose polymer oral liquid, 6 x 1000 mL bottles	1@ 74.40	VF
3136C	triglycerides medium chain and long chain with glucose polymer oral liquid: powder for, 400 g	1@ 36.14	SB
9383W	triglycerides medium chain formula oral liquid: powder for, 30 x 16 g sachets	1@ 61.80	VF
10152H	triglycerides medium chain formula oral liquid: powder for, 400 g	1@ 51.86	SB
10154K		1@ 50.63	NT
10155L		1@ 54.55	VF
1938B		1@ 54.55	VF
8478F		1@ 51.86	SB
3128P	triglycerides medium chain oil: oral, 500 mL	1@ 22.98	SB
10049X	triglycerides medium chain oral liquid, 18 x 250 mL cartons	1@ 188.55	VF
9327X	triglycerides medium chain oral liquid, 1 x 250 mL bottle	1@ 26.00	SB
2666H	trimethoprim 300 mg tablet, 7	7@ 3.85	QA
2666H	trimethoprim 300 mg tablet, 7	7@ 1.96	AF
9165J	tyrosine with carbohydrate containing 1 g tyrosine oral liquid: powder for, 30 x 4 g sachets	1@ 127.40	VF
8448P	ursodeoxycholic acid 250 mg capsule, 100	100@ 155.23	BZ, OA
8133C	valaciclovir 500 mg tablet, 10	10@ 14.98	AF, AS, CH, EA, GN, QA, SZ, TW, TX, UA, VN
9434M	valine with carbohydrate containing 1 g valine oral liquid: powder for, 30 x 4 g sachets	1@ 140.14	VF
9135T	valine with carbohydrate containing 50 mg valine oral liquid: powder for, 30 x 4 g sachets	1@ 127.40	VF
2294R	valproate sodium 100 mg tablet, 100	100@ 12.79	SW
2293Q	valproate sodium 200 mg/5 mL oral liquid, 300 mL	1@ 16.08	SW
2295T		1@ 16.08	SW

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name, Form/Strength	Pack and Price	Manufacturer
2289L	valproate sodium 200 mg tablet: enteric, 100	100@ 7.91	AF, QA, SZ, WA
2289L	valproate sodium 200 mg tablet: enteric, 100	100@ 8.76	SW
2290M	valproate sodium 500 mg tablet: enteric, 100	100@ 15.66	AF, QA, SZ, WA
2290M	valproate sodium 500 mg tablet: enteric, 100	100@ 16.64	SW
3113W	vancomycin 125 mg capsule, 20	20@ 112.92	AS
2270L	vancomycin 1 g injection, 1 x 1 g vial	1@ 4.00	AF, GN, HH, SZ
3114X	vancomycin 250 mg capsule, 20	20@ 216.81	AS
3130R	vancomycin 500 mg injection, 1 x 500 mg vial	1@ 1.99	AF, AS, HH, SZ
3131T		1@ 1.99	AF, AS, HH, SZ
3323X		1@ 1.99	AF, AS, HH, SZ
9129L	varenicline 1 mg tablet, 56	56@ 112.64	PF
9009E	vinorelbine 20 mg capsule, 1	1@ 78.64	FB
9010F	vinorelbine 30 mg capsule, 1	1@ 117.55	FB
9328Y	vitamins, minerals and trace elements with carbohydrate oral liquid: powder for, 200 g	1@ 64.00	SB
9382T	whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, low in protein, phosphate, potassium and lactose oral liquid: powder for, 10 x 100 g sachets	1@ 164.35	VF
2870C	whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, low in protein, phosphate, potassium and lactose oral liquid: powder for, 6 x 400 g cans	1@ 394.46	VF
8587Y	whey protein formula supplemented with amino acids, vitamins and minerals, and low in protein, phosphate, potassium and lactose oral liquid: powder for, 400 g	1@ 66.22	SB
8266C	zolmitriptan 2.5 mg tablet, 2	2@ 11.09	AP
8266C	zolmitriptan 2.5 mg tablet, 2	2@ 9.71	QA, TX
9390F	zonisamide 100 mg capsule, 56	56@ 43.52	SA

Section 4

Drug Tariff

Container Prices

Standard Formulae Preparations

**Table of Codes, Maximum Quantities, and Number of
Repeats for Extemporaneously Prepared
Pharmaceutical Benefits**

Drug Tariff

Drug	Standard	Recovery Prices			
		0.1 g/mL	1 g/mL	10 g/mL	100 g/mL
		\$	\$	\$	\$
Acacia Mucilage (by weight)	APF 15	0.01	0.09	0.70	6.21
Acacia, powdered	BP	0.02	0.16	1.25	11.07
Acetic Acid (6 per cent)	BP	0.01	0.02	0.14	1.23
Acetic Acid (33 per cent)	BP	0.01	0.06	0.46	4.08
Acetone (use as additive only)	BP	0.02	0.15	1.23	10.95
Alum	BP	0.01	0.07	0.57	5.07
Aluminium Acetate Solution	BP	0.02	0.16	1.29	11.48
Anise Water Concentrated 1 in 40 (use as additive only)	BP	0.01	0.07	0.55	4.91
Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.01	0.02	0.19	1.66
Ascorbic Acid (for use only as an ingredient of ferrous sulfate mixtures)	BP	0.24	1.89	15.08	134.04
Aspirin	BP	0.07	0.58	4.66	41.40
Belladonna Tincture	BP	0.09	0.72	5.72	50.83
Benzocaine	BP	0.07	0.57	4.57	40.60
Benzoic Acid	BP	0.06	0.44	3.49	30.98
Benzoic Acid Compound Ointment	APF	0.02	0.12	0.99	8.81
Benzoic Acid Solution	BP	0.02	0.12	0.94	8.33
Benzoin Compound Tincture	BP	0.03	0.25	1.96	17.40
Boric Acid (use as additive only)	BP	0.01	0.11	0.91	8.05
Boric Acid, Olive Oil and Zinc Oxide Ointment	QHF	0.01	0.10	0.77	6.89
Calcium Hydroxide	BP	0.10	0.78	6.22	55.25
Calcium Hydroxide Solution	BP	0.01	0.02	0.15	1.37
Castor Oil (use as additive only)	BP	0.02	0.17	1.34	11.88
Cetomacrogol Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.01	0.04	0.28	2.51
Cetrimide Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.02	0.13	1.04	9.22
Chlorhexidine Acetate (use as additive only)	BP	0.63	5.02	40.16	356.94
Chlorhexidine Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.03	0.21	1.68	14.96
Chloroform (use as additive only)	BP	0.09	0.68	5.42	48.18

Drug	Standard	Recovery Prices			
		0.1 g/mL	1 g/mL	10 g/mL	100 g/mL
		\$	\$	\$	\$
Chloroform Spirit	BP	0.01	0.08	0.64	5.65
Chloroform Water Concentrated 1 in 40	APF 15	0.01	0.10	0.79	7.02
Citric Acid Monohydrate	BP	0.03	0.26	2.08	18.45
Coal Tar	BP	0.23	1.80	14.36	127.60
Coal Tar Solution	BP	0.02	0.13	1.05	9.34
Cocaine Hydrochloride	BP	6.09	48.74	389.90	3465.77
Coconut Oil	BP	0.01	0.10	0.80	7.16
Codeine Linctus	APF	0.01	0.06	0.48	4.26
Codeine Phosphate (may only be prescribed in linctuses, mixtures or mixtures for children)	BP	2.72	21.75	174.00	1546.67
Collodion Flexible	BP	0.18	1.43	11.42	101.50
Dithranol	BP	4.77	38.15	305.20	2712.84
Emulsifying Ointment (for use only as a base combined with active ingredients)	BP	0.01	0.06	0.48	4.27
Ephedrine Hydrochloride (may only be prescribed in nasal instillations)	BP	1.56	12.49	99.90	888.00
Ethanol (90 per cent) (use as additive only)	BP	0.01	0.03	0.27	2.37
Ethanol (96 per cent) (use as additive only)	BP	0.01	0.04	0.29	2.54
Ether Solvent (use as additive only)	BP	0.17	1.34	10.72	95.31
Eucalyptus Oil (use as additive only)	BP	0.02	0.14	1.09	9.65
Ferrous Sulfate	BP	0.16	1.28	10.27	91.25
Formaldehyde Solution	BP	0.12	0.92	7.37	65.55
Gentian Alkaline Mixture	APF	0.01	0.07	0.52	4.63
Glycerol	BP	0.01	0.07	0.59	5.23
Honey Purified (use as additive only)	BP 1993	0.01	0.02	0.17	1.53
Hydroxybenzoate Compound Solution	APF	0.07	0.59	4.72	41.96
Iodine	BP	0.27	2.18	17.40	154.67
Iodine Alcoholic Solution	BP	0.03	0.21	1.69	15.03
Iodine Aqueous Oral Solution	BP	0.04	0.29	2.35	20.88
Kaolin Mixture	BPC 1968	0.01	0.10	0.83	7.37
Kaolin and Opium Mixture	APF 14	0.01	0.09	0.69	6.10
Lactic Acid	BP	0.08	0.64	5.09	45.21
Lavender Spike Oil	BPC 1968	0.11	0.87	6.95	61.75
Liquorice Liquid Extract	BP	0.03	0.25	1.99	17.70
Magnesium Carbonate Light	BP	0.04	0.34	2.74	24.38
Magnesium Sulfate (may only be prescribed for other than oral use)	BP	0.01	0.01	0.11	0.98

Drug	Standard	Recovery Prices			
		0.1 g/mL	1 g/mL	10 g/mL	100 g/mL
		\$	\$	\$	\$
Magnesium Trisilicate	BP	0.04	0.34	2.69	23.95
Menthol, Racemic or Levomenthol	BP	0.26	2.11	16.87	149.94
Methyl Hydroxybenzoate	BP	0.36	2.87	22.94	203.91
Methyl Hydroxybenzoate Solution	APF	0.04	0.30	2.41	21.43
Methylated Industrial Spirit (use as additive only)	BP	0.01	0.04	0.30	2.67
Olive Oil (use as additive only)	BP	0.01	0.10	0.78	6.93
Paraffin Hard	BP	0.04	0.28	2.22	19.76
Paraffin Liquid (may only be prescribed for other than oral use)	BP	0.01	0.03	0.26	2.35
Paraffin Light Liquid	BP	0.02	0.17	1.39	12.38
Paraffin Soft White	BP	0.01	0.04	0.35	3.12
Paraffin Soft Yellow	BP	0.01	0.04	0.35	3.12
Peppermint Oil (use as additive only)	BP	0.14	1.14	9.14	81.21
Peppermint Water Concentrated 1 in 40 (use as additive only)	APF 16	0.04	0.31	2.51	22.35
Phenobarbitone Sodium (may only be prescribed for the treatment of epilepsy)	BP	10.67	85.38	683.00	6071.11
Phenol Liquefied (not available for ear drops)	BP	0.20	1.58	12.67	112.59
Podophyllum Resin	BP	3.50	27.99	223.88	1990.04
Potassium Citrate	BP	0.02	0.18	1.40	12.41
Potassium Iodide	BP	0.11	0.84	6.73	59.80
Potassium Permanganate	BP	0.04	0.32	2.58	22.96
Propyl Hydroxybenzoate	BP	0.28	2.25	17.98	159.82
Propylene Glycol	BP	0.01	0.10	0.80	7.09
Red Syrup	APF 15	0.02	0.13	1.07	9.50
Resorcinol	BP	0.37	2.97	23.76	211.20
Salicylic Acid	BP	0.04	0.29	2.28	20.24
Salicylic Acid Ointment	APF	0.02	0.13	1.01	9.00
Salicylic Acid Ointment	BP	0.02	0.13	1.01	9.00
Simple Ointment (white) (for use only as a base combined with active ingredients)	BP	0.02	0.15	1.16	10.33
Simple Ointment (yellow) (for use only as a base combined with active ingredients)	BP	0.02	0.15	1.16	10.33
Sodium Bicarbonate	BP	0.01	0.09	0.75	6.67
Sodium Chloride	BP	0.02	0.15	1.20	10.64
Sodium Chloride Solution	BP	0.01	0.01	0.08	0.73
Sodium Citrate	BP	0.03	0.25	1.97	17.48

Drug	Standard	Recovery Prices			
		0.1 g/mL	1 g/mL	10 g/mL	100 g/mL
		\$	\$	\$	\$
Sodium Thiosulfate (use as additive only)	BP	0.03	0.24	1.95	17.35
Starch	BP	0.02	0.16	1.27	11.27
Sulfur Ointment (for use only as a base combined with active ingredients)	BP 1980	0.02	0.15	1.20	10.66
Sulfur Precipitated	BP 1980	0.02	0.17	1.35	12.04
Syrup	BP	0.01	0.03	0.23	2.07
Talc Purified, sterilised	BP	0.03	0.27	2.12	18.84
Thymol	BP	0.25	2.03	16.24	144.36
Thymol Compound Mouth Wash	APF 15	0.01	0.10	0.81	7.22
Tragacanth Compound Powder	BP 1980	0.08	0.60	4.76	42.31
Tragacanth Mucilage	APF 13	0.01	0.06	0.44	3.90
Tragacanth Mucilage	BPC 1973	0.01	0.05	0.37	3.32
Tragacanth, powdered	BP	0.25	1.96	15.64	139.05
Trichloroacetic Acid	BP 1980	0.35	2.83	22.63	201.12
Triethanolamine	BP	0.06	0.51	4.08	36.25
Water For Injections, sterilised (b) (extemporaneously prepared eye drops and eye lotions)	BP	—	—	11.37	11.37
Water Purified	BP	0.01	0.01	0.07	0.59
Wool Alcohols Ointment (white) (for use only as a base combined with active ingredients)	BP	0.02	0.15	1.16	10.34
Wool Alcohols Ointment (yellow) (for use only as a base combined with active ingredients)	BP	0.02	0.15	1.16	10.34
Wool Fat	BP	0.02	0.14	1.08	9.58
Wool Fat Hydrous	BP	0.02	0.13	1.05	9.36
Zinc Compound Paste	BP	0.04	0.35	2.81	24.99
Zinc Cream (for use only as a base combined with active ingredients)	BP	0.01	0.08	0.62	5.49
Zinc Oxide	BP	0.02	0.15	1.22	10.81
Zinc and Salicylic Acid Paste	BP	0.02	0.16	1.31	11.62
Zinc Sulfate	BP	0.03	0.25	1.97	17.54

Container Prices

Container Prices	\$
DISPENSING BOTTLES –	
25mL	0.63
50mL	0.58
100mL	0.76
200mL	0.98
500mL	1.34
POISON BOTTLES –	
25mL	0.66
50mL	0.74
100mL	0.77
200mL	1.14
500mL	1.34
SCREW CAP JARS –	
25g	0.97
50g	1.09
100g	1.25
200g	0.89
500g	1.29
DROPPER CONTAINERS –	
15mL polythene	0.89
15mL glass	0.86
Dispensing Fee for Extemporaneously Prepared Benefits	8.80
Additional Fee for Agreed PriceExtemporaneously Prepared Benefits	1.50

Standard Formula Preparations

The following list is not intended to indicate in any way which particular formula an approved pharmacist should use in filling a prescription.

The prices shown in the column 'Dispensed Price for Max. Qty' are for the ingredients, the container and the dispensing fee. The prices shown in the column 'Maximum Recordable Value for Safety Net' are for the ingredients, the container and the dispensing fee and, where applicable, the additional fee for agreed price benefits.

KEY TO REFERENCES:

APF	Australian Pharmaceutical Formulary
BP	British Pharmacopoeia
BPC	British Pharmaceutical Codex
QHF	Queensland Hospital Formulary

Code	Item	Reference	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$
	CREAMS (Maximum Quantity 100 g and 1 Repeat)			
7502W	Salicylic Acid and Sulfur Aqueous	APF	12.55	14.05
	DUSTING POWDERS (Maximum Quantity 100 g and 1 Repeat)			
7458M	Zinc, Starch and Talc	APF 15 & BPC 1973	26.50	28.00
	EAR DROPS (Maximum Quantity 15 mL and 2 Repeats)			
7642F	Aluminium Acetate	APF	10.91	12.41
7643G	Aluminium Acetate	BP	11.63	13.13
7314Y	Sodium Bicarbonate	APF & BP	10.16	11.66
7313X	Spirit	APF	9.94	11.44
	INHALATIONS (Maximum Quantity 50 mL and 1 Repeat)			
7484X	Benzoin and Menthol	APF	21.44	22.94
7308P	Menthol	APF	12.99	14.49
7310R	Menthol and Eucalyptus	BP 1980	13.83	15.33
	LINCTUSES CONTAINING CODEINE PHOSPHATE (Maximum Quantity 100 mL and 0 Repeats)			
7530H	Codeine	APF	13.82	15.32
	LOTIONS (Maximum Quantity 200 mL and 2 Repeats)			
7709R	Aluminium Acetate Aqueous	APF	12.35	13.85
	MIXTURES, OTHER (Maximum Quantity 200 mL and 4 Repeats)			
7604F	Gentian Alkaline	APF	19.05	20.55
7348R	Kaolin	BPC 1968	24.52	26.02
7301G	Kaolin and Opium	APF 14	21.97	23.47
7342K	Magnesium Trisilicate	BPC 1968	18.68	20.18
7343L	Magnesium Trisilicate and Belladonna	BPC 1968	24.26	25.76

Code	Item	Reference	Dispensed Price for Max. Qty	Maximum Recordable Value for Safety Net
			\$	\$
	MOUTH WASHES (Maximum Quantity 200 mL and 1 Repeat)			
7457L	Thymol Compound	APF 15	24.39	25.89
	OINTMENTS (Maximum Quantity 100 g and 1 Repeat)			
7914M	Benzoic Acid Compound	APF & BP	18.86	20.36
7902X	Boric Acid, Olive Oil and Zinc Oxide	QHF	16.94	18.44
7926E	Salicylic Acid	APF	19.05	20.55
7928G	Salicylic Acid (extemporaneous formula)	BP	19.05	20.55
	PAINTS (Maximum Quantity 25 mL and 1 Repeat)			
7567G	Podophyllin Compound	APF 16 & BP	119.29	37.70
7568H	Salicylic Acid	APF	38.72	37.70
	PASTES, OTHER (Maximum Quantity 100 g and 1 Repeat)			
7558T	Zinc	APF & BP	35.04	36.54
	POWDER FOR INTERNAL USE (Maximum Quantity 100 g and 2 Repeats)			
7545D	Magnesium Trisilicate	BP	33.64	35.14

—CONTAINER RATES ARE INCLUDED—

**Table of Codes, Maximum Quantities, and Number of Repeats
for Extemporaneously Prepared Benefits**

Code	Preparation	Maximum Quantity	Number of Repeats
13Q	Creams	100 g	1
48M	Dusting Powders	100 g	1
15T	Ear Drops	15 mL	2
19B	Eye Drops containing Cocaine Hydrochloride	15 mL	..
22E	Eye Drops, Other	15 mL	5
23F	Eye Lotions	200 mL	2
29M	Inhalations	50 mL	1
64J	Linctuses containing Codeine Phosphate	100 mL	..
34T	Linctuses, Other	100 mL	2
39C	Lotions	200 mL	2
65K	Mixtures containing Codeine Phosphate	200 mL	..
40D	Mixtures, Other	200 mL	4
66L	Mixtures for Children containing Codeine Phosphate	100 mL	..
41E	Mixtures for Children, Other	100 mL	4
30N	Mouth Washes	200 mL	1
42F	Nasal Instillations	15 mL	2
43G	Ointments, Waxes	100 g	1
44H	Paints	25 mL	1
63H	Pastes containing Cocaine Hydrochloride	25 g	..
45J	Pastes, Other	100 g	1
49N	Powders for Internal Use	100 g	2
52R	Solutions	200 mL	2

Special Note: Purified Water BP is the minimum requirement for water in all PBS extemporaneous preparations.



Australian Government

Department of Health

REPATRIATION SCHEDULE OF PHARMACEUTICAL BENEFITS

1 May 2015

The benefits listed in this Schedule may only be prescribed to Department of Veterans' Affairs beneficiaries holding a:

- Repatriation Health Card For All Conditions (gold); or
- Repatriation Health Card For Specific Conditions (white); or
- Repatriation Pharmaceutical Benefits Card (orange);

BENEFICIARIES' ENTITLEMENT CARDS AND ELIGIBILITY FOR REPATRIATION PHARMACEUTICAL BENEFITS

Gold card This card is issued to those veterans of Australia's defence force, their widows/widowers and dependants entitled to treatment for all medical conditions.	 The image shows a sample Gold Repatriation Health Card. It is a yellowish-gold card with the Australian Government coat of arms at the top left. The text reads: 'Repatriation Health Card For All Conditions Within Australia'. A large red 'SAMPLE' watermark is diagonally across the center. Below the watermark, it says 'File No.' followed by a blank line. At the bottom right, it says 'Card expires or on recall'.
White card A White Card is issued to Australian veterans or mariners under the Veterans' Entitlements Act 1986 with: • an accepted war or service-caused injury or disease; • malignant cancer (neoplasia) whether war-caused or not; • pulmonary tuberculosis whether war-caused or not; • post-traumatic stress disorder whether war-caused or not; or • anxiety and/or depression whether war-caused or not.	 The image shows a sample White Repatriation Health Card. It is a white card with the Australian Government coat of arms at the top left. The text reads: 'Repatriation Health Card - For Specific Conditions'. A large red 'SAMPLE' watermark is diagonally across the center. Below the watermark, it says 'File No.' followed by a blank line. At the bottom right, it says 'Card expires or on recall'.
Orange card Orange Repatriation pharmaceutical benefits cards are issued to Commonwealth and allied veterans and mariners who: • have qualifying service from World War I or II and • are aged 70 or over and • have been resident in Australia for 10 years or more.	 The image shows a sample Orange Repatriation Pharmaceutical Benefits Card. It is an orange card with the Australian Government coat of arms at the top left. The text reads: 'Repatriation Pharmaceutical Benefits Card'. A large red 'SAMPLE' watermark is diagonally across the center. Below the watermark, it says 'File No.' followed by a blank line. At the bottom left, it says 'PHARMACEUTICALS ONLY'. At the bottom right, it says 'Card expires or on recall'.

For more information go to the Department of Veterans' Affairs website:
http://www.dva.gov.au/service_providers/treatment_cards/Pages/index.aspx

RPBS Explanatory Notes

Introduction

The Australian Repatriation System

- The Australian Repatriation system is based primarily on the principle of compensation to veterans and eligible dependants for injury or death related to war service. In certain cases, treatment is also provided for accepted injuries or conditions that are not service-related or have occurred as a result of other than war service.
- Through the *Veterans' Entitlements Act 1986* the Department of Veterans' Affairs provides programs of compensation, income support and treatment for eligible veterans and their dependants. One of the defined benefits for eligible veterans is the Repatriation Pharmaceutical Benefits Scheme. This range of medications and dressings is more comprehensive than is available through the Pharmaceutical Benefits Scheme.

RPBS prescribing provisions

- Unless otherwise stated, Repatriation Pharmaceutical Benefits Scheme (RPBS) prescriptions must conform with the requirements of Pharmaceutical Benefits Scheme (PBS) prescriptions, as detailed in Section 1 – Explanatory Notes in the *Schedule of Pharmaceutical Benefits* book. The prescriber shall ensure that a prescription contains the following details:
 - the category of benefit, i.e., RPBS, by placing a cross in the relevant box;
 - the patient's full name and address;
 - the prescription date;
 - the DVA file number of the patient as evidence of entitlement;
 - in the case of authority prescriptions, the Authority approval number or the four digit streamlined authority code;
 - the item, form, strength, quantity and directions;
 - the number of repeats, if applicable;
 - indicate when brand substitution is not permitted; and
 - the name, signature, the prescriber number and address of the prescriber.

Prior Approval Arrangements

- The prior approval of the Department is required to prescribe the following:
 - 'Authority required' items (excluding 'Authority required (STREAMLINED)' items) listed in either the PBS or RPBS Schedule;
 - increased quantities and/or repeats of items listed in either the PBS or RPBS Schedule;
 - items listed under section 100 of the *National Health Act 1953*; and
 - other items not listed in either Schedule (non-Schedule items).
- The above items are to be prescribed on the common PBS/RPBS authority prescription form in accordance with the directions stated in the Explanatory Notes in the *Schedule of Pharmaceutical Benefits* (See also information regarding dental prescribing and prescribing by optometrists under the RPBS in these Notes.)
- All Authority required prescriptions and requests for non-Schedule items must receive prior approval from the Department. This can be achieved by either:
 - using the Department's national free call number 1800 552 580; or
 - by mailing the written authority prescription to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) at the reply paid address shown at the end of these RPBS Explanatory Notes.

Prior approval is not required from DVA to prescribe an Authority required (STREAMLINED) item (except where increased quantities and/or repeats are required). Instead the authority prescription form must include a four digit streamlined authority code.

- Some requests for prior approval (including some non-Schedule items) need to be referred by VAPAC to the Repatriation Pharmaceutical Reference Committee for consideration. In such cases a VAPAC pharmacist will advise the prescriber to submit a request in writing that provides the following information:
 - A current clinical report on the patient's condition (such as age, co-morbidities, renal, liver failure) and clinical reports including pathology, biochemistry, diagnostic and other investigations if appropriate.
 - Details of past and current therapy for the condition. Include details of PBS, RPBS and non-Schedule items utilised, and the results of those therapies.
 - Details of the proposed treatment regimen. Include intended dose and duration of treatment and objective measures of response.

- When the proposed use of the item is outside the TGA-approved indications for use in Australia, provide copies of articles from peer reviewed publications supporting the proposed treatment.
- Signed, informed patient consent where the item is to be used for a non-TGA-approved indication.
- For items without Australian marketing approval, a copy of the TGA Special Access Scheme approval to prescribe the drug.
- Requests for prior approval to prescribe a non-Schedule (PBS or RPBS) item that is of the same therapeutic class (ATC level 3) as an item that is listed on the Schedule, will not be approved unless unequivocal clinical evidence is presented to demonstrate that the requested item is essential for effective treatment of the nominated patient.
- A pharmacist should not supply an item prescribed on an RPBS Authority Prescription Form unless the form has been approved and stamped by VAPAC, or has been endorsed by the prescriber with a telephone Authority approval number provided by VAPAC. The Department of Human Services will not accept RPBS Authority prescriptions that have not been approved by the Department of Veterans' Affairs for payment.

Palliative Care Drugs

- The following medications may be available, or made available in increased quantities or doses under prior approval arrangements for use only in the palliative care of terminal disease:
 - clonazepam
 - cyclizine
 - dexamethasone
 - disodium pamidronate
 - fentanyl
 - glycopyrrolate
 - hyoscine butylbromide
 - hyoscine hydrobromide
 - ketamine
 - midazolam
 - octreotide
- For further information telephone VAPAC on 1800 552 580.

Dental Prescribing

- Under Department of Veterans' Affairs arrangements, financial responsibility for pharmaceutical benefits prescribed by a Local Dental Officer (LDO) is limited to treatment to which holders of the following cards are entitled:
 - a Gold Repatriation Health Card – For All Conditions; or
 - a White Repatriation Health Card – For Specific Conditions; or
 - an Orange Repatriation Pharmaceutical Benefits Card.
- Where possible the LDO shall prescribe in accordance with the provisions governing dental prescribing under the Pharmaceutical Benefits Scheme (PBS).
- Prescriptions for PBS Dental Schedule items for Gold, White and Orange Card holders are to be dispensed at the PBS concessional rate. Claims for payment by the dispensing pharmacist are to be included with other Repatriation prescriptions. The card holder is required to meet the cost of any applicable brand premium.
- When a non-PBS Dental Schedule item is prescribed for an eligible card holder, the LDO's private prescription form should be used. The dispensing pharmacist may charge the patient the full cost of the prescription. The patient may claim a refund for the full cost of a non-Schedule item from the Department if an itemised receipt (not a cash register receipt) and a copy of the prescription are provided.

Prescribing by optometrists

- Optometrists approved as 'PBS prescribers' may write RPBS prescriptions as outlined in Section 1 for medicines listed in Section 2 of the PBS Schedule as pharmaceutical benefits for optometrical use.
- Medicines in the optometrist list include non-Authority and Authority required items. Procedures for obtaining VAPAC approval to prescribe 'Authority required' optometrist items or increased quantities and/or repeats of optometrist items under the RPBS are the same as indicated under prior approval arrangements above.

- The list of medicines for prescribing by optometrists under the RPBS is the same as applies under the PBS. There are no optometrist listings in the RPBS Schedule for prescribing for veterans only. There is no provision for optometrist prescribers to request approval to prescribe items that are not included in the PBS optometrist list (non-Schedule items).
- Optometrist PBS/RPBS prescription forms are for use for prescribing non-Authority or Authority required optometrist items under the RPBS with one item per form only.

Provisions governing pricing and payment for RPBS benefits

Introduction

- Unless otherwise stated, the pricing and payment principles and arrangements for approved pharmacists supplying pharmaceutical benefits under the RPBS will be the same as those arrangements applying under the PBS.
- Where a pharmaceutical benefit that is not listed on the PBS or RPBS Schedule is dispensed on an RPBS Authority prescription, a pharmacist will price the benefit and enter the serial number, prescription identifying number and price on the sticker or stamp imprint affixed to the prescription.

Pricing of Schedule Items

- Items supplied under the RPBS from the PBS Schedule, both ready-prepared and extemporaneously-prepared, will be paid on the same basis as benefits supplied under the PBS. Items supplied under the RPBS from the Repatriation Schedule, including wound dressings, will be paid on the basis of the price as given in the Repatriation Pharmaceutical Benefits section (Section 1 – RPBS Schedule, Drugs, Medicines and Dressings) of the *Schedule of Pharmaceutical Benefits*.

Pricing of Non-Schedule Ready Prepared Items

- Non-Schedule ready-prepared items are to be priced on the basis of the invoiced, GST-exclusive wholesale price to pharmacists plus the appropriate PBS mark-up and the PBS dispensing fee. Where the item price to pharmacists is greater than \$100.00, a copy of the invoice pertaining to the supply of that item is to be submitted together with the appropriate copy of the authority prescription as part of the claim for payment.

Pricing of Non-Schedule Extemporaneously Prepared Items

- When an ingredient drug is not listed in the PBS Drug Tariff, the recovery price will be based on the invoiced wholesale price to pharmacists, increased by a mark-up of 100%, calculated in accordance with the directions contained in the pricing instructions for pricing of PBS extemporaneously-prepared benefits in this Schedule. The price paid by the pharmacist for the commercial pack from which the ingredient is used shall be endorsed on the prescription form.

Miscellaneous Pricing Rules

- The price to pharmacists used as the basis of pricing will be the invoiced, GST-exclusive price from the wholesaler.
- If multiple quantities of a manufacturer's original pack are supplied, the PBS mark-up is applied to the price to pharmacist of each pack and then totalled. The PBS dispensing fee, and the PBS dangerous drug fee if applicable, are then added to the total of the marked-up prices.
- When the quantity prescribed corresponds with the quantity of a manufacturer's original pack, in no circumstances will the price payable for one pack exceed that payable for multiples or combinations of packs to supply the quantity prescribed.
- The list of ingredient drugs and prices included in the PBS Drug Tariff are common to both the PBS and RPBS. Certain restrictions apply regarding the prescribing and dispensing of some of these ingredient drugs as pharmaceutical benefits, e.g., use as additive only.
- For items prescribed generically, including non-Schedule and wound dressings, the pharmacist should indicate on the prescription the quantity and brand supplied. If prescriptions are not endorsed, the Department will pay the lowest priced acceptable product available.

General

Packaging Material, Postage or Freight

- Payment to a pharmacist for the costs of packaging materials, postage or freight required to supply a pharmaceutical benefit is to be paid by the patient, who may then claim reimbursement from the Department through the provision of a pharmacist's itemised receipt.

Payment for Items Supplied at Short Intervals

- For all items dispensed at specific short intervals of time, the Department will pay a separate PBS dispensing fee for each occasion that the drug is supplied and which is acknowledged on receipt by the patient or agent.
- The price payable on the items supplied will be based on the individual dose quantity supplied. Where applicable, a PBS dangerous drug fee and a minimum container charge will be payable for each supply.

Receipts for Patient Charges

- Where a charge is paid by a patient in any of the circumstances of paragraphs 13 or 24, the pharmacist is required to provide a printed receipt to the patient with the details of the items or services provided, the amount paid, date of supply and the patients name and address. The patient may apply for reimbursement from the Department.

Special Patient Contributions

- The Special Patient Contribution for items listed as Special Pharmaceutical Benefits in the PBS Schedule is not payable by veterans entitled to pharmaceutical benefits under the RPBS. Eligible veterans receiving Special Pharmaceutical Benefits under the RPBS are required to pay only the concessional patient contribution and any applicable brand premium. If a Safety Net Entitlement card is held, the veteran should receive a Special Pharmaceutical Benefit free of charge, subject to any brand premium applicable. The Department of Human Services will reimburse the dispensing pharmacist the total dispensed price, less the concessional patient contribution and/or brand premium if applicable.

Therapeutic Group Premiums — Authority Processing

- Items attracting a therapeutic group premium are dual listed. Dispensing pharmacists are therefore required to select the appropriate code for those items that are dual listed as authority and non-authority items, in order to correctly charge the patient and claim from the Department of Human Services. Those authority prescriptions that grant exemption from a therapeutic group premium will have the letters 'TPX' at the beginning of the telephone Authority approval number, or, in the case of a written approval, will be stamped with the words "This prescription does not attract a therapeutic group premium".

DEPARTMENT OF VETERANS' AFFAIRS

Authority Prescription Applications

Applications for authority to prescribe under the Repatriation Pharmaceutical Benefits Scheme (RPBS) should be sent to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) using the free postal service:

REPLY PAID 9998
VAPAC (Veterans' Affairs Pharmaceutical Advisory Centre)
Department of Veterans' Affairs
GPO Box 9998
BRISBANE QLD 4001

For RPBS enquiries and telephone approvals 24 hours a day the Freecall number is:

1800 552 580

Departmental pharmacists answer applications for prior approval for non-Schedule items and Authority application calls.

SUMMARY OF CHANGES

Repatriation Pharmaceutical Benefits

Additions

Addition – Brand

4806Y *Hydrosorb 900854, HR* – **DRESSING HYDROGEL SHEET**, dressing hydrogel sheet 10 cm x 10 cm dressing, 5

Deletions

Deletion – Brand

4806Y *Aquaclear 900796, HR* – **DRESSING HYDROGEL SHEET**, dressing hydrogel sheet 10 cm x 10 cm dressing, 5

Therapeutic Index for RPBS

ALIMENTARY TRACT AND METABOLISM	1244
STOMATOLOGICAL PREPARATIONS.....	1244
STOMATOLOGICAL PREPARATIONS.....	1244
DRUGS FOR ACID RELATED DISORDERS.....	1244
ANTACIDS.....	1244
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	1244
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	1244
BELLADONNA AND DERIVATIVES, PLAIN	1244
DRUGS FOR CONSTIPATION.....	1244
DRUGS FOR CONSTIPATION.....	1244
ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS.....	1245
ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS.....	1245
VITAMINS.....	1246
VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12	1246
VITAMIN B-COMPLEX, INCL. COMBINATIONS	1246
MINERAL SUPPLEMENTS	1246
CALCIUM.....	1246
OTHER MINERAL SUPPLEMENTS	1246
BLOOD AND BLOOD FORMING ORGANS	1248
ANTITHROMBOTIC AGENTS.....	1248
ANTITHROMBOTIC AGENTS.....	1248
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS.....	1248
IRRIGATING SOLUTIONS	1248
CARDIOVASCULAR SYSTEM.....	1249
VASOPROTECTIVES	1249
AGENTS FOR TREATMENT OF HEMORRHOIDS AND ANAL FISSURES FOR TOPICAL USE.....	1249
DERMATOLOGICALS	1250
ANTIFUNGALS FOR DERMATOLOGICAL USE.....	1250
ANTIFUNGALS FOR TOPICAL USE.....	1250
ANTIFUNGALS FOR SYSTEMIC USE.....	1250
EMOLLIENTS AND PROTECTIVES.....	1251
EMOLLIENTS AND PROTECTIVES.....	1251
PROTECTIVES AGAINST UV-RADIATION	1251
ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.....	1252
ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.....	1252
ANTIPSORIATICS	1252
ANTIPSORIATICS FOR TOPICAL USE	1252
ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE.....	1252
ANTIBIOTICS FOR TOPICAL USE	1252
CHEMOTHERAPEUTICS FOR TOPICAL USE	1252
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS.....	1253
CORTICOSTEROIDS, PLAIN	1253
ANTISEPTICS AND DISINFECTANTS	1253
ANTISEPTICS AND DISINFECTANTS	1253
OTHER DERMATOLOGICAL PREPARATIONS.....	1253
OTHER DERMATOLOGICAL PREPARATIONS.....	1253
GENITO URINARY SYSTEM AND SEX HORMONES.....	1256
GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	1256
ANTIINFECTIVES AND ANTISEPTICS, EXCL. COMBINATIONS WITH CORTICOSTEROIDS	1256
OTHER GYNECOLOGICALS.....	1256
OTHER GYNECOLOGICALS.....	1256
UROLOGICALS.....	1256
UROLOGICALS.....	1256
DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY.....	1257
ANTIINFECTIVES FOR SYSTEMIC USE	1259
ANTIBACTERIALS FOR SYSTEMIC USE	1259

MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS	1259
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	1260
ANTINEOPLASTIC AGENTS	1260
ANTIMETABOLITES.....	1260
IMMUNOSUPPRESSANTS.....	1260
IMMUNOSUPPRESSANTS.....	1260
MUSCULO-SKELETAL SYSTEM.....	1261
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	1261
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS.....	1261
TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN.....	1261
TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	1261
DRUGS FOR TREATMENT OF BONE DISEASES.....	1261
DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION	1261
NERVOUS SYSTEM	1263
ANALGESICS.....	1263
OPIOIDS	1263
OTHER ANALGESICS AND ANTIPYRETICS	1263
PSYCHOLEPTICS	1264
ANXIOLYTICS.....	1264
HYPNOTICS AND SEDATIVES	1264
OTHER NERVOUS SYSTEM DRUGS	1265
DRUGS USED IN ADDICTIVE DISORDERS	1265
ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS.....	1266
ANTHELMINTICS	1266
ANTINEMATODAL AGENTS	1266
RESPIRATORY SYSTEM.....	1267
NASAL PREPARATIONS.....	1267
DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE	1267
NASAL DECONGESTANTS FOR SYSTEMIC USE.....	1267
COUGH AND COLD PREPARATIONS	1267
EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS.....	1267
COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS.....	1267
ANTIHISTAMINES FOR SYSTEMIC USE	1268
ANTIHISTAMINES FOR SYSTEMIC USE.....	1268
SENSORY ORGANS.....	1269
OPHTHALMOLOGICALS.....	1269
DECONGESTANTS AND ANTIALLERGICS.....	1269
OTOLOGICALS	1269
OTHER OTOLOGICALS	1269
VARIOUS.....	1270
ALL OTHER THERAPEUTIC PRODUCTS.....	1270
ALL OTHER THERAPEUTIC PRODUCTS.....	1270
ALL OTHER NON-THERAPEUTIC PRODUCTS.....	1273
ALL OTHER NON-THERAPEUTIC PRODUCTS.....	1273

Section 1

Drugs, Medicines and Dressings

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	

ALIMENTARY TRACT AND METABOLISM

STOMATOLOGICAL PREPARATIONS

STOMATOLOGICAL PREPARATIONS

Antiinfectives and antiseptics for local oral treatment

CHLORHEXIDINE

4161B	chlorhexidine gluconate 0.2% (2 mg/mL) mouthwash, 250 mL	‡1	..	..	12.23	6.10	Plaqacide	OB
4204G	chlorhexidine gluconate 0.2% (2 mg/mL) mouthwash, 300 mL	‡1	..	..	15.62	6.10	Savacol Mouth and Throat Rinse	OM

DRUGS FOR ACID RELATED DISORDERS

ANTACIDS

Calcium compounds

CALCIUM CARBONATE + GLYCINE

Note

For patients with chronic renal failure.

4055K	calcium carbonate 420 mg + glycine 180 mg tablet: chewable, 100	2	5	..	*23.52	6.10	Titralac	MM

Combinations and complexes of aluminium, calcium and magnesium compounds

ALUMINIUM HYDROXIDE WITH MAGNESIUM HYDROXIDE AND SIMETHICONE

4118R	ALUMINIUM HYDROXIDE with MAGNESIUM HYDROXIDE and SIMETHICONE Oral suspension 400 mg-400 mg-30 mg per 5 mL, 500 mL, 1	2	5	..	*22.98	6.10	Mylanta Double Strength	JT
4453J	ALUMINIUM HYDROXIDE with MAGNESIUM HYDROXIDE and SIMETHICONE Tablet 400 mg-400 mg-40 mg, 100	2	5	..	*46.46	6.10	Mylanta Double Strength	JT

DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

Synthetic anticholinergics, esters with tertiary amino group

MEBEVERINE

4328T	mebeverine hydrochloride 135 mg tablet, 90	1	..	..	27.25	6.10	^a Colese	AF
				..	32.43	6.10	^a Colofac	GO

BELLADONNA AND DERIVATIVES, PLAIN

Belladonna alkaloids, semisynthetic, quaternary ammonium compounds

HYOSCINE BUTYLBROMIDE

4279F	hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules	1	..	..	24.55	6.10	Buscopan	BY

DRUGS FOR CONSTIPATION

DRUGS FOR CONSTIPATION

Softeners, emollients

DOCUSATE

4200C	docusate sodium 50 mg tablet, 100	1	2	..	14.65	6.10	Coloxyl 50	FM

Contact laxatives

DOCUSATE + SENNOSIDE B

4028B	docusate sodium 50 mg + sennoside B 8 mg tablet, 100	1	2	..	14.75	6.10	Soflax	GN

ALIMENTARY TRACT AND METABOLISM

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10177P	docusate sodium 50 mg + sennoside B 8 mg tablet, 90	1	2	..	13.48	6.10	Pharmacy Action Laxative with Senna	GQ
DOCUSATE + SENNOSIDES								
4198Y	docusate sodium 50 mg + sennosides 11.27 mg tablet, 90	1	2	..	13.52	6.10	^a Co-Senna	PP
				..	17.03	6.10	^a Coloxyl with Senna	FM
SENNOSIDE B								
4455L	sennoside B 7.5 mg tablet, 100	1	1	..	12.94	6.10	^a Senna-Gen	PP
				..	14.20	6.10	^a Senokot	RC
Bulk-forming laxatives								
ISPAGHULA HUSK DRY								
4285M	ispaghula husk dry 3.5 g oral liquid: powder for, 30 x 3.5 g sachets	‡1	1	..	17.98	6.10	Fybogel	RC
PSYLLIUM HUSK POWDER								
4422R	PSYLLIUM HYDROPHILIC MUCILLOID Oral powder (non-flavoured) 336 g, 1	‡1	1	..	18.36	6.10	Fibre Health Natural Granular	PP
				..	22.01	6.10	Metamucil Natural Granular	PY
4419N	PSYLLIUM HYDROPHILIC MUCILLOID Oral powder (orange-flavoured, sugar-free) 283 g, 1	‡1	1	..	22.01	6.10	Metamucil Orange Smooth	PY
RHAMNUS FRANGULA + STERCULIA								
4558X	rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g	‡1	1	..	26.71	6.10	Normacol Plus	NE
Enemas								
SORBITOL + CITRATE + LAURYL SULFOACETATE SODIUM								
4462W	sorbitol 3.125 g/5 mL + citrate sodium dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 4 x 5 mL	‡1	..	..	12.44	6.10	Micolette	AE
							MicroLax	JT
Other drugs for constipation								
GLYCEROL								
Restricted benefit								
Short-term use when oral laxative therapy has failed or is inappropriate								
4246L	glycerol 2.8 g suppository, 12	3	..	..	*22.15	6.10	Petrus Pharmaceuticals Pty Ltd	PP

ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS

ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS

Peripherally acting antiobesity products

ORLISTAT

Authority required

For the treatment of obese patients.

Total treatment will not exceed 12 months from initial application.

Patients are eligible for 1 continuous treatment in a lifetime.

The patient must be receiving, or enrolled to receive, professional dietetic and weight management advice (where this is available).

Initial treatment for patients who meet the following criteria to qualify:

(a) Body Mass Index (BMI) greater than or equal to 35 with no known co-morbidities; or

(b) BMI greater than or equal to 30 with 1 or more of the following co-morbidities:

(i) diabetes;

(ii) ischaemic heart disease;

(iii) psychiatric conditions;

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	(iv) hypertension. The prescriber must provide the following: (a) initial body weight; and (b) BMI. Continuing treatment for patients who have previously been issued with an authority prescription for orlistat. After 3 months and up to 6 months following commencement of orlistat treatment, patient's initial body weight must have been reduced by 2.5 kg or 2.5% (whichever is the lesser). Continuing treatment for patients who have previously been issued with an authority prescription for orlistat. After 6 months and up to 12 months following commencement of orlistat treatment, patient's initial body weight must have been reduced by 5 kg or 5% (whichever is the lesser) Note The patient should be ideally enrolled in an exercise program and be receiving supplemental vitamins.							
4570M	orlistat 120 mg capsule, 84	1	2	..	140.50	6.10	Xenical	RO

VITAMINS

VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12

Vitamin B1, plain

THIAMINE

4043T	thiamine hydrochloride 100 mg tablet, 100	1	2	..	10.45	6.10	Betavit	PP

VITAMIN B-COMPLEX, INCL. COMBINATIONS

Vitamin B-complex, plain

CYANOCOBALAMIN + FERRIC PYROPHOSPHATE + LYSINE + PYRIDOXINE + THIAMINE

4493L	cyanocobalamin 25 microgram/10 mL + iron (as ferric pyrophosphate) 10 mg/10 mL + lysine hydrochloride 300 mg/10 mL + pyridoxine hydrochloride 5 mg/10 mL + thiamine hydrochloride 10 mg/10 mL oral liquid, 200 mL	1	2	..	13.68	6.10	Accomin Adult Tonic	PF

MINERAL SUPPLEMENTS

CALCIUM

Calcium

CALCIUM

Restricted benefit

Hyperphosphataemia in chronic renal failure

4094L	CALCIUM Tablet (chewable) 500 mg (as carbonate), 60	4	1	..	*29.24	6.10	^a Cal-500	PP

4142B	CALCIUM Tablet 600 mg (as carbonate), 120	2	1	..	*22.54	6.10	^a Cal-Sup CAL-600	IA PP

CALCIUM

Restricted benefit

Hypocalcaemia

Restricted benefit

Osteoporosis

Restricted benefit

Proven calcium malabsorption

4333C	CALCIUM Tablet (chewable) 500 mg (as carbonate), 60	2	1	..	*18.00	6.10	^a Cal-500	PP

4082W	CALCIUM Tablet 600 mg (as carbonate), 120	1	1	..	14.65	6.10	^a Cal-Sup CAL-600	IA PP

OTHER MINERAL SUPPLEMENTS

Magnesium

MAGNESIUM ASPARTATE DIHYDRATE

ALIMENTARY TRACT AND METABOLISM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
<u>Restricted benefit</u>								
Patients with documented hypomagnesaemia								
4321K	magnesium aspartate dihydrate 500 mg (equivalent to 37.4 mg of magnesium) tablet, 50	1	..	..	14.04	6.10	Mag-Sup	PP
				..	14.73	6.10	Magmin	BB

BLOOD AND BLOOD FORMING ORGANS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	

BLOOD AND BLOOD FORMING ORGANS

ANTITHROMBOTIC AGENTS

ANTITHROMBOTIC AGENTS

Platelet aggregation inhibitors excl. heparin

ASPIRIN

Note

The enteric coated preparations are for patients with a significant risk of gastrointestinal bleeding.

4078P	aspirin 100 mg capsule: enteric, 84	1	1	..	14.96	6.10	Astrix	YN
4077N	aspirin 100 mg tablet: enteric, 84	1	1	..	14.05	6.10	^a Cartia	AS
							^a Pharmacy Action Low Dose Aspirin	GQ
4076M	ASPIRIN aspirin 100 mg tablet, 90	1	1	..	16.01	6.10	Cardiprin 100	RC

CLOPIDOGREL

Authority required

For use in patients pre- and post-angioplasty

Note

Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution.

10169F	clopidogrel 75 mg tablet, 28	1	3	..	15.70	6.10	^a Clopidogrel GH	GQ
4179Y	clopidogrel 75 mg tablet, 28	1	3	..	15.70	6.10	^a APO-Clopidogrel	TX
							^a Chem mart Clopidogrel	CH
							^a Iscover	AV
							^a Piax	AF
							^a Plavix	SW
							^a Terry White Chemists Clopidogrel	TW

BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS

IRRIGATING SOLUTIONS

Salt solutions

SODIUM CHLORIDE

4460R	sodium chloride 0.9% (4.5 g/500 mL) solution, 1 x 500 mL bottle	‡1	2	..	10.67	6.10	Baxter Healthcare Pty Ltd	BX
4461T	sodium chloride 0.9% (9 g/1000 mL) solution, 1 x 1000 mL bottle	‡1	2	..	10.99	6.10	Baxter Healthcare Pty Ltd	BX

CARDIOVASCULAR SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

CARDIOVASCULAR SYSTEM

VASOPROTECTIVES

AGENTS FOR TREATMENT OF HEMORRHOIDS AND ANAL FISSURES FOR TOPICAL USE

Other agents for treatment of hemorrhoids and anal fissures for topical use

ZINC OXIDE + PERU BALSAM + BENZYL BENZOATE

4039N	zinc oxide 10.75% (107.5 mg/g) + peru balsam 1.88% (18.8 mg/g) + benzyl benzoate 1.25% (12.5 mg/g) ointment, 50 g	‡1	1	..	14.78	6.10	Anusol	JT
4040P	zinc oxide 300 mg + peru balsam 50 mg + benzyl benzoate 33 mg suppository, 12	‡1	1	..	13.69	6.10	Anusol	JT

DERMATOLOGICALS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	

DERMATOLOGICALS

ANTIFUNGALS FOR DERMATOLOGICAL USE

ANTIFUNGALS FOR TOPICAL USE

*Antibiotics***NYSTATIN**

4001N	nystatin 100 000 international units/g cream, 15 g	‡1	1	..	12.83	6.10	Mycostatin	FM

*Imidazole and triazole derivatives***CLOTRIMAZOLE**

4004R	clotrimazole 1% (10 mg/g) cream, 20 g	‡1	1	..	8.78	6.10	^a Pharmacy Action Anti-Fungal Cream	GQ
				..	9.18	6.10	^a Clonea	AF

KETOCONAZOLE**Restricted benefit**

Severe seborrhoeic dermatitis

4007X	ketoconazole 2% (20 mg/g) shampoo, 100 mL	‡1	..	..	19.71	6.10	Sebizole	GN
4008Y	ketoconazole 2% (20 mg/g) shampoo, 60 mL	‡1	..	..	18.65	6.10	Nizoral 2%	JT

MICONAZOLE

4341L	miconazole 2% solution, 30 mL	‡1	1	..	19.81	6.10	Daktarin Tincture	JT
4454K	miconazole nitrate 2% (20 mg/g) cream, 30 g	‡1	1	..	15.13	6.10	Daktarin	JT
3400Y	miconazole nitrate 2% (20 mg/g) cream, 40 g	‡1	1	..	14.02	6.10	Resolve Thrush	EO

*Other antifungals for topical use***AMOROLFINE****Restricted benefit**

Onychomycosis

4010C	amorolfine 5% application, 5 mL	‡1	1	..	86.85	6.10	Aporyl	TX
				..	96.48	6.10	Loceryl	GA

CICLOPIROX**Restricted benefit**

Severe seborrhoeic dermatitis

4106D	ciclopirox olamine 1.5% (15 mg/g) shampoo, 60 mL	‡1	..	..	19.08	6.10	Stieprox Liquid	GK

TERBINAFINE**Restricted benefit**

Tinea pedis

4463X	terbinafine 1% gel, 15 g	‡1	..	..	23.69	6.10	Lamisil DermGel	NC
4473K	terbinafine hydrochloride 1% cream, 15 g	‡1	1	..	22.23	6.10	Lamisil	NC

TOLNAFTATE

4481W	tolnaftate 0.07% (700 microgram/g) spray, 100 g	‡1	..	..	15.43	6.10	Tinaderm	BN

ANTIFUNGALS FOR SYSTEMIC USE

*Antifungals for systemic use***TERBINAFINE**

DERMATOLOGICALS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
Authority required								
Onychomycosis due to dermatophyte infection proven by microscopy or culture and confirmed by an approved pathology provider								
4011D	terbinafine 250 mg tablet, 42	1	1	..	38.82	6.10	^a GenRx Terbinafine	GX
							^a Lamisil (Novartis Pharmaceuticals Australia Pty Limited)	NV
							^a Tamsil	QA
							^a Terbinafine GH	GQ
							^a Terbinafine Sandoz	SZ
							^a Tinasil	AF

EMOLLIENTS AND PROTECTIVES

EMOLLIENTS AND PROTECTIVES

Silicone products

DIMETHICONE-350 + GLYCEROL

Restricted benefit

For colostomy and ileostomy use

Restricted benefit

For use by paraplegic and quadriplegic patients

Restricted benefit

For use with surgical appliances

4551M	dimethicone-350 15% (150 mg/g) + glycerol 2% (20 mg/g) cream, 500 g	‡1	..	..	26.75	6.10	Silic 15	EO
4556T	dimethicone-350 15% (150 mg/g) + glycerol 2% (20 mg/g) cream, 75 g	‡1	..	..	12.87	6.10	Silic 15	EO

Soft paraffin and fat products

WOOL ALCOHOLS

4041Q	wool alcohols 6% (60 mg/g) ointment, 100 g	‡1	1	..	14.52	6.10	Eucerin	BE

Carbamide products

UREA

4042R	urea 10% (100 mg/g) cream, 100 g	‡1	2	..	12.53	6.10	Aquacare H.P.	AG
				..	12.79	6.10	Urederm	IA
				..	13.11	6.10	Calmurid	OL

Other emollients and protectives

CARMELLOSE SODIUM + GELATIN + PECTIN

4518T	carmellose sodium 16.7% + gelatin 16.7% + pectin 16.7% paste: oromucosal, 5 g	‡1	..	..	12.19	6.10	Orabase	QA

SKIN EMOLLIENT

4122Y	SKIN EMOLLIENT Bath oil 500 mL, 1	‡1	2	..	17.69	6.10	Alpha Keri Bath Oil	MT
				..	20.10	6.10	QV Bath Oil	EO
				..	20.19	6.10	Hamilton Skin Therapy Oil	KY
4107E	SKIN EMOLLIENT Lotion 500 mL, 1	‡1	2	..	17.69	6.10	Alpha Keri Lotion	MT

PROTECTIVES AGAINST UV-RADIATION

Protectives against UV-radiation for topical use

SUNSCREENS

4307Q	SUNSCREENS Cream 75 g, 1	‡1	2	..	18.39	6.10	Sunsense Sensitive SPF 50+	EO
4546G	SUNSCREENS Lotion (non-alcoholic) 125 mL, 1	‡1	2	..	16.32	6.10	Aquasun Lotion SPF 18	PF
				..	18.39	6.10	Sunsense Ultra SPF 50+	EO

DERMATOLOGICALS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	

ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.

ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.

Anesthetics for topical use**LIGNOCAINE**

4308R	lignocaine hydrochloride anhydrous 2% (20 mg/mL) oral liquid, 200 mL	‡1	..	..	95.37	6.10	Xylocaine Viscous	AP

Other antipruritics**PINE TAR WITH TRIETHANOLAMINE LAURYL SULFATE****Note**

For patients who have failed to respond to simple moisturising agents.

4408B	PINE TAR with TRIETHANOLAMINE LAURYL SULFATE Solution 23 mg-60 mg per mL (2.3%-6%), 500 mL, 1	‡1	2	..	23.26	6.10	Pinetarsol	EO

ANTIPSORIATICS

ANTIPSORIATICS FOR TOPICAL USE

Tars**COAL TAR SOLUTION + PHENOL + SULFUR-PRECIPITATED**

4505D	coal tar solution 5% + phenol 0.5% + sulfur-precipitated 0.5% gel, 30 g	‡1	2	..	16.36	6.10	Egopsoryl-TA	EO

ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE

ANTIBIOTICS FOR TOPICAL USE

Other antibiotics for topical use**MUPIROCIN****Restricted benefit**

For the topical treatment of secondarily infected traumatic skin lesions

4348W	mupirocin 2% (20 mg/g) cream, 15 g	‡1	..	..	17.59	6.10	Bactroban	GK
4350Y	mupirocin 2% (20 mg/g) ointment, 15 g	‡1	..	..	17.59	6.10	Bactroban	GK

CHEMOTHERAPEUTICS FOR TOPICAL USE

Antivirals**PODOPHYLLOTOXIN****Authority required**

For the treatment of ano-genital warts

4390C	podophyllotoxin 0.15% (1.5 mg/g) cream, 5 g	‡1	..	..	53.00	6.10	Wartec Cream	GK
4566H	podophyllotoxin 0.5% solution, 3.5 mL	‡1	..	..	40.09	6.10	Condyline Paint	NQ

Other chemotherapeutics**INGENOL MEBUTATE****Authority required**

Solar keratosis

Clinical criteria:

Patient must require topical drug therapy on the face and scalp as field treatment for clinically visible and subclinical lesions where other standard treatments are inappropriate.

2464Q	ingenol mebutate 0.015% gel, 3 x 470 mg tubes	1	..	..	139.60	6.10	Picato	LO

INGENOL MEBUTATE**Authority required**

Solar (actinic) keratosis

DERMATOLOGICALS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
Clinical criteria:								
Patient must require topical drug therapy as field treatment for clinically visible and subclinical lesions where other standard treatments are inappropriate.								
2468X	ingenol mebutate 0.05% gel, 2 x 470 mg tubes	1	..	..	139.60	6.10	Picato	LO

CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS

CORTICOSTEROIDS, PLAIN

Corticosteroids, potent (group III)

BETAMETHASONE VALERATE

4131K	betamethasone (as valerate) 0.1% (1 mg/g) cream, 30 g	\$1	2	..	22.77	6.10	Betnovate	QA
4132L	betamethasone (as valerate) 0.1% (1 mg/g) ointment, 30 g	\$1	2	..	22.77	6.10	Betnovate	QA

MOMETASONE

Note

Application to large areas of skin for longer than four weeks is not recommended.

4342M	mometasone furoate 0.1% (1 mg/g) cream, 50 g	\$1	..	..	33.82	6.10	Elocon	MK
4343N	mometasone furoate 0.1% (1 mg/g) ointment, 50 g	\$1	..	..	33.82	6.10	Elocon	MK

ANTISEPTICS AND DISINFECTANTS

ANTISEPTICS AND DISINFECTANTS

Iodine products

POVIDONE-IODINE

4411E	povidone-iodine 10% solution, 100 mL	\$1	..	..	22.45	6.10	Betadine Antiseptic Liquid	SW

OTHER DERMATOLOGICAL PREPARATIONS

OTHER DERMATOLOGICAL PREPARATIONS

Medicated shampoos

COAL TAR SOLUTION + TAR + SALICYLIC ACID

4447C	coal tar solution 1% (10 mg/g) + tar 1% (10 mg/g) + salicylic acid 2% (20 mg/g) solution, 250 mL	\$1	2	..	19.18	6.10	Sebitar	EO

SALICYLIC ACID + BENZALKONIUM CHLORIDE + ALCOHOL + COAL TAR SOLUTION + POLYOXYETHYLENE ETHERS

4560B	SALICYLIC ACID with COAL TAR SOLUTION Scalp cleanser 20 mg-50 mg per mL (2%-5%), 200 mL, 1	\$1	2	..	20.72	6.10	Ionil-T	GA

SELENIUM SULFIDE

4452H	selenium sulfide 2.5% (25 mg/mL) shampoo, 125 mL	\$1	..	..	14.48	6.10	Selsun	DQ

TAR + CADE OIL + COAL TAR + ARACHIS OIL EXTRACT OF COAL TAR

4405W	tar 0.3% (300 microgram/mL) + cade oil 0.03% (300 microgram/mL) + coal tar 0.01% (100 microgram/mL) + arachis oil extract of coal tar 0.3% (3 mg/mL) lotion, 300 mL	\$1	2	..	24.48	6.10	Polytar	GK

Wart and anti-corn preparations

LACTIC ACID + SALICYLIC ACID

4386W	lactic acid 16.7% (167 mg/mL) + salicylic acid 16.7% (167 mg/mL) application, 15 mL	\$1	..	..	18.49	6.10	Duofilm Solution	GK

Other dermatologicals

DERMATOLOGICALS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
DICLOFENAC								
<u>Authority required</u>								
For the management of actinic keratoses in patients where other standard treatments are inappropriate, and topical drug therapy is required as field treatment for clinically visible and subclinical lesions								
<u>Note</u>								
Maximum quantity of four tubes (original + 3 repeats) in 12 months.								
4046Y	diclofenac sodium 3% gel, 25 g	‡1	3	..	58.53	6.10	Solaraze 3% Gel	CS
ICHTHAMMOL								
<u>Note</u>								
For patients who have failed to respond to simple moisturising agents.								
4281H	ichthammol Cream 5 mg-10 mg-10 mg per g (0.5%-1%-1%), 50 g, 1	‡1	2	..	18.44	6.10	Egoderm Cream	EO
ICHTHAMMOL + ZINC OXIDE								
<u>Note</u>								
For patients who have failed to respond to simple moisturising agents.								
4280G	ichthammol 1% (10 mg/g) + zinc oxide 15% (150 mg/g) ointment, 50 g	‡1	2	..	18.44	6.10	Egoderm Ointment	EO
IMIQUIMOD								
<u>Authority required</u>								
Solar keratosis								
Clinical criteria:								
Patient must require topical drug therapy on the face and scalp as field treatment for clinically visible and subclinical lesions where other standard treatments are inappropriate.								
<u>Note</u>								
Pharmaceutical benefits that have the form imiquimod single use sachets and pharmaceutical benefits that have the form imiquimod multi-use pump are equivalent for the purposes of substitution.								
4134N	imiquimod 5% cream, 12 x 250 mg sachets	1	1	..	135.72	6.10	^a Aldara	IA
10106X	imiquimod 5% cream, 2 x 2 g pump packs	1	1	..	135.72	6.10	^a Aldiq	QA
							^a APO-Imiquimod	TX
							^a Aldara Pump	IA
IMIQUIMOD								
<u>Authority required</u>								
Primary treatment of histopathologically confirmed superficial basal cell carcinoma where other standard treatments are inappropriate and topical drug therapy is required								
4559Y	imiquimod 5% cream, 12 x 250 mg sachets	1	1	..	135.72	6.10	^a Aldara	IA
							^a Aldiq	QA
							^a APO-Imiquimod	TX
PANTHENOL								
<u>Note</u>								
To be used in conjunction with the scalp cleanser salicylic acid with coal tar solution and pine tar (code 4447C).								
4510J	panthenol conditioner, 200 g	‡1	2	..	14.59	6.10	SebiRinse	EO
PARAFFIN LIGHT LIQUID + COCOAMPHODIACETATE DISODIUM								
4549K	paraffin light liquid 3.5% (35 mg/mL) + cocoamphodiacetate disodium 3% (30 mg/mL) lotion, 500 mL	‡1	2	..	21.08	6.10	Hamilton Skin Therapy Wash	KY
ZINC OXIDE + MAIZE STARCH + CHLORPHENESIN + TALC-PURIFIED								
4497Q	zinc oxide 25% (250 mg/g) + maize starch 55.85% (558.5 mg/g) + chlorphenesin 1% (10 mg/g) + talc-purified 18.07% (180.7 mg/g) powder: dusting, 100 g	‡1	1	..	12.59	6.10	Z.S.C.	QA

DERMATOLOGICALS

GENITO URINARY SYSTEM AND SEX HORMONES

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

GENITO URINARY SYSTEM AND SEX HORMONES

GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS

ANTIINFECTIVES AND ANTISEPTICS, EXCL. COMBINATIONS WITH CORTICOSTEROIDS

Antibiotics

4013F	NYSTATIN nystatin 20 000 international units/g vaginal cream, 75 g	‡1	1	..	14.13	6.10	Nilstat	QA

Imidazole derivatives

4016J	CLOTRIMAZOLE clotrimazole 1% (10 mg/g) cream, 35 g	‡1	..	..	14.03	6.10	^a Pharmacy Action FemCream	GQ
				..	15.42	6.10	^a APO-Clotrimazole 6 Day Cream	TX
4017K	clotrimazole 2% (20 mg/g) cream, 20 g	‡1	..	..	15.42	6.10	APO-Clotrimazole 3 Day Cream	TX

OTHER GYNECOLOGICALS

OTHER GYNECOLOGICALS

4434J	ACETIC ACID + HYDROXYQUINOLINE + RICINOLEIC ACID acetic acid 0.94% + hydroxyquinoline sulfate 0.025% + ricinoleic acid 0.75% vaginal gel, 100 g	‡1	..	..	33.24	6.10	Aci-Jel	CU

UROLOGICALS

UROLOGICALS

Drugs used in erectile dysfunction

ALPROSTADIL

Authority required

Males with vasculogenic, psychogenic or neurogenic erectile dysfunction

Clinical criteria:

Patient must have a specific accepted war-caused or service-related disability.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

10031Y	alprostadil 10 microgram injection [1 x 10 microgram vial] (&) inert substance diluent [1 syringe], 1 pack	6	3	..	*105.82	6.10	Caverject	PF
10030X	alprostadil 20 microgram injection [1 x 20 microgram vial] (&) inert substance diluent [1 syringe], 1 pack	6	3	..	*133.18	6.10	Caverject	PF

SILDENAFIL

Authority required

Specific accepted war-caused or service-related disabilities for males with vasculogenic, psychogenic or neurogenic erectile dysfunction.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats

4586J	sildenafil 100 mg tablet, 4	1	5	..	73.33	6.10	^a APO-Sildenafil	TX
							^a Chem mart Sildenafil	CH
							^a Sildenafil GH	GQ
							^a Terry White Chemists Sildenafil	TW
				..	86.02	6.10	^a Vasafil 100	QA
							^a Silaran	RA
							^a Viagra	PF
4584G	sildenafil 25 mg tablet, 4	1	5	..	55.21	6.10	^a Vasafil 25	QA
				..	55.22	6.10	^a APO-Sildenafil	TX

GENITO URINARY SYSTEM AND SEX HORMONES

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
4585H	sildenafil 50 mg tablet, 4	1	5	..	64.32	6.10	^a Viagra	PF
				..	68.31	6.10	^a APO-Sildenafil	TX
				..	80.03	6.10	^a Vasafil 50 ^a Viagra	QA PF

TADALAFIL

Authority required

Specific accepted war-caused or service-related disabilities for males with vasculogenic, psychogenic or neurogenic erectile dysfunction.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats

4596X	tadalafil 10 mg tablet, 4	1	5	..	98.96	6.10	Cialis	LY
4597Y	tadalafil 20 mg tablet, 4	1	5	..	98.96	6.10	Cialis	LY

VARDENAFIL

Authority required

Specific accepted war-caused or service-related disabilities for males with vasculogenic, psychogenic or neurogenic erectile dysfunction.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats

4290T	varденаfil 10 mg tablet, 4	1	5	..	73.13	6.10	Levitra	BN
4302K	varденаfil 20 mg tablet, 4	1	5	..	83.86	6.10	Levitra	BN

Other urologicals

BICARBONATE + CITRATE + TARTARIC ACID

Restricted benefit

For relief of urinary symptoms when antibiotic or other therapy alone is inappropriate

4049D	sodium bicarbonate 1.76 g + citrate sodium 630 mg + citrate 720 mg + tartaric acid 890 mg oral liquid: powder for, 28 x 4 g sachets	1	4	..	13.89	6.10	Uracol	GN
							Ural Sachets	QA

DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY

Alpha-adrenoreceptor antagonists

ALFUZOSIN

Authority required

Treatment of benign prostatic hyperplasia where surgery is inappropriate, or where other drug treatment has failed or is contraindicated

4277D	alfuzosin hydrochloride 10 mg tablet: modified release, 30 tablets	1	5	..	63.70	6.10	Xatral SR	SW

DUTASTERIDE + TAMSULOSIN

Authority required

Benign prostatic hyperplasia

Clinical criteria:

Patient must be one in whom surgery is inappropriate; OR

Patient must have failed to respond to other drug treatment or other drug treatment must be contraindicated.

10102Q	dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram capsule: modified release, 30	1	5	..	35.63	6.10	Duodart 500ug/400ug	GK

TAMSULOSIN

Authority required

Treatment of benign prostatic hyperplasia where surgery is inappropriate, or where other drug treatment has failed or is contraindicated

4070F	tamsulosin hydrochloride 400 microgram tablet: modified release, 30	1	5	..	63.70	6.10	Flomaxtra	LS
							Tamsulosin Sandoz SR	SZ

TERAZOSIN

GENITO URINARY SYSTEM AND SEX HORMONES

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
<u>Authority required</u>								
Treatment of benign prostatic hyperplasia where surgery is inappropriate, or where other drug treatment has failed or is contraindicated								
4396J	terazosin 1 mg tablet [7 tablets] (& terazosin 2 mg tablet [7 tablets], 14	1	..	..	20.39	6.10	Hytrin	GO
4399M	terazosin 10 mg tablet, 28	1	5	..	86.40	6.10	Hytrin	GO
4397K	terazosin 2 mg tablet, 28	1	5	..	42.03	6.10	Hytrin	GO
4398L	terazosin 5 mg tablet, 28	1	5	..	58.53	6.10	Hytrin	GO

Testosterone-5-alpha reductase inhibitors

DUTASTERIDE

Authority required

Benign prostatic hyperplasia

Clinical criteria:

Patient must be one in whom surgery is inappropriate; OR

Patient must have failed to respond to other drug treatment or other drug treatment must be contraindicated.

10095H	dutasteride 500 microgram capsule, 30	1	5	..	30.77	6.10	Avodart	GK

FINASTERIDE

Authority required

Treatment of benign prostatic hyperplasia where surgery is inappropriate, or where other drug treatment has failed or is contraindicated

4303L	finasteride 5 mg tablet, 28	1	5	..	91.60	6.10	^a Finpro	RZ
							^a Pharmacy Choice Finasteride	RI
4233T	finasteride 5 mg tablet, 30	1	5	..	78.03	6.10	^a Finasteride GH 5	GQ
				..	97.66	6.10	^a Finasteride RBX	RA
				..	102.45	6.10	^a Finnacar	QA
							^a APO-Finasteride	TX
							^a Finasta	SZ
							^a Finasteride Alphapharm	AF
							^a Finasteride-GA 5	GN
							^a Pharmacor Finasteride 5	CR
							^a Proscar	MK

ANTIINFECTIVES FOR SYSTEMIC USE

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

ANTIINFECTIVES FOR SYSTEMIC USE

ANTIBACTERIALS FOR SYSTEMIC USE

MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

Macrolides

AZITHROMYCIN

Restricted benefit

Upper and lower respiratory tract infections

[illegible]

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

ANTINEOPLASTIC AGENTS

ANTIMETABOLITES

Pyrimidine analogues

FLUOROURACIL

4222F	fluorouracil 5% (50 mg/g) cream, 20 g	1	..	..	60.96	6.10	Efudix	IA

IMMUNOSUPPRESSANTS

IMMUNOSUPPRESSANTS

Tumor necrosis factor alpha (TNF-) inhibitors

INFLIXIMAB

Authority required

Initial treatment, in combination with methotrexate, of specific accepted war-caused or service-related disability of refractory rheumatoid arthritis. Initial treatment may be prescribed by rheumatologists or consultant physicians for the reduction of signs and symptoms and prevention of structural joint damage in adult patients with active rheumatoid arthritis who satisfy all of the following criteria:

- (1) (a) Proven raised erythrocyte sedimentation rate (ESR) and/or C-reactive protein (CRP); and
- (1) (b) Proven erosive rheumatoid arthritis without end-stage disease;
- (2) Failure of an adequate trial of methotrexate and 2 other disease modifying anti-rheumatic drugs (such as sulfasalazine, hydroxychloroquine, leflunomide or cyclosporin) — unless these drugs were contraindicated or intolerance had developed;
- (3) No history of active tuberculosis requiring treatment in the last 3 years;
- (4) No history of opportunistic infection in the last 2 months;
- (5) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Infliximab (Remicade) RPBS Authority Application - Supporting Information form (contact the VAPAC on 1800 552 580 for a copy of the form)

Authority required

Continuing treatment, in combination with methotrexate, of specific accepted war-caused or service-related disability of refractory rheumatoid arthritis. Continuing treatment may be prescribed by rheumatologists or consultant physicians, following initial therapy of 3 doses, in patients who satisfy the following criteria:

- (1) There is improvement in ESR and/or CRP; and
- (2) An ACR20 (American College of Rheumatology) response is achieved by 14 weeks after the commencement of therapy.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Infliximab (Remicade) RPBS Authority Application - Supporting Information form (contact the VAPAC on 1800 552 580 for a copy of the form)

Note

Any queries concerning the arrangements to prescribe infliximab may be directed to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) on 1800 552 580.

Written applications for authority to prescribe infliximab should be forwarded to:

Reply Paid 9998

Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC)

Department of Veterans' Affairs

GPO Box 9998

BRISBANE QLD 4001

4284L	infliximab 100 mg injection, 1 x 100 mg vial	1	2	..	847.32	6.10	Remicade	JC

MUSCULO-SKELETAL SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	

MUSCULO-SKELETAL SYSTEM

ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS

ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS

Acetic acid derivatives and related substances

DICLOFENAC + MISOPROSTOL

Authority required

Patients requiring an NSAID in whom a risk of upper gastrointestinal complications is high or with a history of peptic ulcer disease

4190M	diclofenac sodium 50 mg + misoprostol 200 microgram tablet, 60	1	2	..	38.12	6.10	Arthrotec 50	PF

TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN

TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN

Preparations with salicylic acid derivatives

METHYL SALICYLATE

4026X	methyl salicylate 25% (0.25 mL/mL) liniment, 100 mL	1	1	..	10.28	6.10	Gold Cross	BI
4023R	methyl salicylate 50% (500 mg/g) ointment, 100 g	1	1	..	12.51	6.10	Gold Cross	BI

METHYL SALICYLATE + MENTHOL + EUCALYPTUS OIL

4022Q	methyl salicylate 25% (250 mg/g) + menthol 4% (40 mg/g) + eucalyptus oil 10% (100 mg/g) cream, 100 g	1	1	..	14.36	6.10	Gold Cross	BI

DRUGS FOR TREATMENT OF BONE DISEASES

DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

Bisphosphonates

RISEDRONATE

Authority required

For preservation of bone mineral density in patients on long-term glucocorticoid therapy where patients are undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day. Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more and demonstrate that the patient is osteopenic (bone mineral density t-score of less than -1.0)

2191H	RISEDRONATE SODIUM Tablet 35 mg (enteric coated), 4	1	5	..	42.11	6.10	Actonel EC	UA
4444X	risedronate sodium 35 mg tablet, 4	1	5	..	42.11	6.10	^a Acris Once-a-Week	AF
							^a APO-Risedronate	TX
							^a Risedronate-GA	GN
							^a Risedronate Sandoz	SZ
							^a Risedro once a week	QA
4443W	risedronate sodium 5 mg tablet, 28	1	5	..	42.11	6.10	Actonel	UA

Bisphosphonates, combinations

ALENDRONATE + COLECALCIFEROL

Authority required

For preservation of bone mineral density in patients on long-term glucocorticoid therapy where patients are undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day. Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more and demonstrate that the patient is osteopenic (bone mineral density t-score of less than -1.0)

2224C	alendronate 70 mg + colecalciferol 140 microgram tablet, 4	1	5	..	45.51	6.10	^a Alendronate plus D3-DRLA	RZ
				..	48.00	6.10	^a Fosamax Plus 70 mg/140 mcg	MK
2194L	alendronate 70 mg + colecalciferol 70 microgram tablet, 4	1	5	..	45.51	6.10	Fosamax Plus	MK

ALENDRONATE + COLECALCIFEROL (&) CALCIUM CARBONATE

MUSCULO-SKELETAL SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
<u>Authority required</u>								
For preservation of bone mineral density in patients on long-term glucocorticoid therapy where patients are undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day. Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more and demonstrate that the patient is osteopenic (bone mineral density t-score of less than -1.0)								
2273P	alendronate 70 mg + colecalciferol 140 microgram tablet [4] (&) calcium (as carbonate) 500 mg tablet [48], 1 pack	‡1	5	..	45.51	6.10	Fosamax Plus D-Cal	MK
RISEDRONATE (&) CALCIUM CARBONATE								
<u>Authority required</u>								
For preservation of bone mineral density in patients on long-term glucocorticoid therapy where patients are undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day. Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more and demonstrate that the patient is osteopenic (bone mineral density t-score of less than -1.0)								
2220W	RISEDRONATE SODIUM and CALCIUM CARBONATE Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium), 1	‡1	5	..	45.73	6.10	Actonel EC Combi	UA
4059P	risedronate sodium 35 mg tablet [4] (&) calcium (as carbonate) 500 mg tablet [24], 28	‡1	5	..	45.73	6.10	Acris Combi	AF
RISEDRONATE (&) CALCIUM CARBONATE + COLECALCIFEROL								
<u>Authority required</u>								
For preservation of bone mineral density in patients on long-term glucocorticoid therapy where patients are undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day. Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more and demonstrate that the patient is osteopenic (bone mineral density t-score of less than -1.0)								
2254P	RISEDRONATE SODIUM and CALCIUM CARBONATE with COLECALCIFEROL Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms, 1	‡1	5	..	45.73	6.10	Actonel EC Combi D	UA

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

NERVOUS SYSTEM

ANALGESICS

OPIOIDS

Natural opium alkaloids

MORPHINE

Restricted benefit

Chronic severe disabling pain not responding to non-narcotic analgesics

Caution

The risk of drug dependence is high.

Note

Authorities for increased maximum quantities and/or repeats will be granted only for

- (i) chronic severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain where treatment has been initiated by a specialist with appropriate expertise in pain management.

4349X	morphine sulfate 200 mg tablet: modified release, 28 tablets	1	..	..	122.20	6.10	MS Contin	MF

OTHER ANALGESICS AND ANTIPYRETICS

Salicylic acid and derivatives

ASPIRIN + CODEINE

4286N	aspirin 300 mg + codeine phosphate 8 mg tablet: dispersible, 40	1	2	..	14.52	6.10	Aspalgin 40	QA

Anilides

PARACETAMOL + CODEINE

4170L	paracetamol 500 mg + codeine phosphate 15 mg tablet, 20	1	2	..	10.07	6.10	Prodeine 15	SW
4275B	paracetamol 500 mg + codeine phosphate 8 mg tablet, 40	1	2	..	11.03	6.10	Panamax Co. 40	SW
4171M	paracetamol 500 mg + codeine phosphate 8 mg tablet, 50	1	2	..	13.20	6.10	Codalgin	FM
10186D	paracetamol 500 mg + codeine phosphate hemihydrate 15 mg tablet, 20	1	2	..	10.07	6.10	Pharmacy Action Paracetamol Plus Codeine	GQ

Other analgesics and antipyretics

GABAPENTIN

Authority required

To be approved for the treatment of refractory neuropathic pain not controlled by other drugs

4591P	gabapentin 100 mg capsule, 100	1	5	..	12.95	6.10	^a APO-Gabapentin	TX
							^a Gabapentin Aspen 100	FM
							^a Gabatine 100	QA
							^a Neurontin	PF
							^a Nupentin 100	AF
4592Q	gabapentin 300 mg capsule, 100	1	5	..	27.43	6.10	^a DBL Gabapentin	HH
							^a Gabapentin 300	CR
							^a Gabapentin Aspen 300	FM
							^a Gabatine 300	QA
							^a Gantin	GN
							^a GenRx Gabapentin	GX
							^a Neurontin	PF
							^a Nupentin 300	AF
4593R	gabapentin 400 mg capsule, 100	1	5	..	34.94	6.10	^a DBL Gabapentin	HH
							^a Gabapentin 400	CR
							^a Gabapentin Aspen 400	FM
							^a Gabatine 400	QA

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
4594T	gabapentin 600 mg tablet, 100	1	5	..	50.16	6.10	a Gantin	GN
							a GenRx Gabapentin	GX
							a Neurontin	PF
							a Nupentin 400	AF
							a Gabapentin Aspen 600	FM
4595W	gabapentin 800 mg tablet, 100	1	5	..	63.81	6.10	a Gabatine 600	QA
							a GenRx Gabapentin	GX
							a Neurontin	PF
							a Nupentin Tabs	AF
							a Gabapentin Aspen 800	FM
							a Gabatine 800	QA
							a Gantin	GN
							a GenRx Gabapentin	GX
							a Neurontin	PF
							a Nupentin Tabs	AF

PSYCHOLEPTICS

ANXIOLYTICS

Benzodiazepine derivatives

BROMAZEPAM

Authority required

Patients with terminal disease

Authority required

Patients with refractory phobic or anxiety states

Note

For short-term use and palliative care. This drug should not be used as the first line of treatment. Other PBS-listed benzodiazepines should have been adequately tried and found to be ineffective or inappropriate. Authorities for increased quantities and/or repeats may be granted to patients with terminal disease, and other patients who have been shown to be dependent on this item by an unsuccessful attempt at gradual withdrawal.

4150K	bromazepam 3 mg tablet, 30	2	..	..	*29.82	6.10	Lexotan	RO
4151L	bromazepam 6 mg tablet, 30	2	..	..	*36.44	6.10	Lexotan	RO

Azapirodecanedione derivatives

BUSPIRONE

Authority required

For the short-term treatment of anxiety

4145E	buspirone hydrochloride 10 mg tablet, 50	1	..	..	55.18	6.10	Buspar	QA
4144D	buspirone hydrochloride 5 mg tablet, 50	1	..	..	38.33	6.10	Buspar	QA

HYPNOTICS AND SEDATIVES

Benzodiazepine derivatives

FLUNITRAZEPAM

Authority required

Patients with terminal disease

Authority required

Patients with refractory phobic or anxiety states

Note

For short-term use and palliative care. This drug should not be used as the first line of treatment. Other PBS-listed benzodiazepines should have been adequately tried and found to be ineffective or inappropriate. Authorities for increased quantities and/or repeats may be granted to patients with terminal disease, and other patients who have been shown to be dependent on this item by an unsuccessful attempt at gradual withdrawal.

4216X	flunitrazepam 1 mg tablet, 30	1	..	..	15.22	6.10	Hypnodorm	AF

Benzodiazepine related drugs

ZOPICLONE

NERVOUS SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
<u>Restricted benefit</u>								
For the short-term treatment of insomnia								
4522B	zopiclone 7.5 mg tablet, 30	1	..	..	22.10	6.10	^a Imrest	AF
				..	25.25	6.10	^a Imovane	SW

OTHER NERVOUS SYSTEM DRUGS

DRUGS USED IN ADDICTIVE DISORDERS

Drugs used in nicotine dependence

NICOTINE

Authority required

Patients who have indicated that they are ready to cease smoking and who have entered a support and counselling program

Note

Studies have shown that successful therapy with this drug is enhanced by patient participation in a support and counselling program.

4577X	nicotine 10 mg/16 hours patch, 7	2	..	..	*55.12	6.10	Nicorette Patch	JT
4572P	nicotine 14 mg/24 hours patch, 7	2	..	..	*54.90	6.10	QuitX	AF
4578Y	nicotine 15 mg/16 hours patch, 7	2	2	..	*69.08 *60.30	6.10 6.10	Nicabate CQ 14 Nicorette Patch	GC JT
4573Q	nicotine 21 mg/24 hours patch, 7	2	2	..	*58.02	6.10	QuitX	AF
4576W	nicotine 5 mg/16 hours patch, 7	2	..	..	*69.08 *51.14	6.10 6.10	Nicabate CQ 21 Nicorette Patch	GC JT
4571N	nicotine 7 mg/24 hours patch, 7	2	..	..	*51.74	6.10	QuitX	AF

ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Maximum	Brand Name and Manufacturer
					Price for Max. Qty \$	Recordable Value for Safety Net \$	

ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS

ANTHELMINTICS

ANTINEMATODAL AGENTS
Benzimidazole derivatives

MEBENDAZOLE								
4325P	mebendazole 100 mg tablet, 6	1	..	..	15.26	6.10	Vermox	IA

RESPIRATORY SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

RESPIRATORY SYSTEM

NASAL PREPARATIONS

DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE

Sympathomimetics, plain

OXYMETAZOLINE

4378K	oxymetazoline hydrochloride 0.05% (500 microgram/mL) nasal spray, 15 mL	‡1	..	..	17.49	6.10	Drixine	BN
4379L	oxymetazoline hydrochloride 0.05% (500 microgram/mL) nasal spray, 18 mL	‡1	..	..	17.10	6.10	Logicin Rapid Relief	QA

Antiallergic agents, excl. corticosteroids

CROMOGLYCATE

4468E	cromoglycate sodium 2% (20 mg/mL) nasal spray, 26 mL	‡1	5	..	23.25	6.10	Rynacrom	SW

LEVOCABASTINE

4311X	levocabastine 0.05% (500 microgram/mL) nasal spray, 100 actuations	‡1	2	..	18.58	6.10	Livostin	JT

Corticosteroids

BUDESONIDE

Restricted benefit

Severe intractable rhinitis

4092J	budesonide 64 microgram/actuation nasal spray, 120 actuations	‡1	..	..	37.51	6.10	Budamax Aqueous	PM

Other nasal preparations

IPRATROPIUM

Restricted benefit

Severe intractable rhinorrhoea, associated with perennial rhinitis, unresponsive to insufflated nasal steroids

4089F	ipratropium bromide anhydrous 21 microgram/actuation nasal spray, 180 actuations	‡1	5	..	23.93	6.10	Atrovent Nasal Aqueous	BY
4090G	ipratropium bromide anhydrous 42 microgram/actuation nasal spray, 180 actuations	‡1	5	..	30.81	6.10	Atrovent Nasal Forte	BY

NASAL DECONGESTANTS FOR SYSTEMIC USE

Sympathomimetics

PSEUDOEPHEDRINE

4029C	pseudoephedrine hydrochloride 60 mg tablet, 12	1	..	..	10.61	6.10	^a Pharmacy Action Sinus & Nasal Decongestant Relief	GQ
				..	11.36	6.10	^a Logicin Sinus	QA

COUGH AND COLD PREPARATIONS

EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS

Expectorants

AMMONIUM + SENEGA ROOT

4074K	ammonium bicarbonate 25 mg/mL + senega root 25 mg/mL oral liquid, 200 mL	‡1	4	..	9.52	6.10	Gold Cross	BI

COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS

Opium alkaloids and derivatives

PHOLCODINE

RESPIRATORY SYSTEM

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
4071G	pholcodine 1 mg/mL oral liquid, 100 mL	‡1	2	..	9.36	6.10	Gold Cross	BI
				..	14.95	6.10	Duro-Tuss	IA

ANTI-HISTAMINES FOR SYSTEMIC USE

ANTI-HISTAMINES FOR SYSTEMIC USE

Piperazine derivatives

CETIRIZINE

4175R	cetirizine hydrochloride 10 mg tablet, 30	1	..	..	26.28	6.10	^a Pharmacy Action Cetrelief	GQ
				..	29.99	6.10	^a Alzene	AF
				..	33.21	6.10	Zilarex	SZ
				..	39.79	6.10	^a Zyrtec	JT

Other antihistamines for systemic use

FEXOFENADINE

4238C	fexofenadine hydrochloride 120 mg tablet, 30	1	..	..	29.76	6.10	^a Xergic	AF
				..	35.05	6.10	^a Fexal	SZ
				..	47.47	6.10	^a Telfast 120	SW
4237B	fexofenadine hydrochloride 60 mg tablet, 20	3	..	..	*55.33	6.10	Telfast	SW

LORATADINE

4313B	loratadine 10 mg tablet, 30	1	..	..	29.07	6.10	^a Pharmacy Action Lorastyne	GQ
				..	33.33	6.10	^a Allereze	AF
				..	43.99	6.10	^a Lorano	SZ
				..	46.26	6.10	^a Claratyne	BN

SENSORY ORGANS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	

SENSORY ORGANS

OPHTHALMOLOGICALS

DECONGESTANTS AND ANTIALLERGICS

Sympathomimetics used as decongestants

NAPHAZOLINE								
4035J	naphazoline hydrochloride 0.1% eye drops, 15 mL	‡1	1	..	15.43	6.10	Albalon Liquifilm	AG
NAPHAZOLINE + ANTAZOLINE								
4032F	naphazoline hydrochloride 0.05% + antazoline phosphate 0.5% eye drops, 15 mL	‡1	1	..	15.14	6.10	Albalon-A	AG

Other antiallergics

LEVOCABASTINE								
4310W	levocabastine 0.05% eye drops, 4 mL	‡1	1	..	18.58	6.10	Livostin	JT

OTOLOGICALS

OTHER OTOLOGICALS

Indifferent preparations

CARBAMIDE PEROXIDE								
4176T	carbamide peroxide 6.5% ear drops, 12 mL	‡1	..	..	17.66	6.10	Ear Clear for Ear Wax Removal	KY
DICHLOROBENZENE WITH CHLORIBUTOL AND ARACHIS OIL								
4180B	DICHLOROBENZENE with CHLORIBUTOL and ARACHIS OIL Ear drops, ortho-dichlorobenzene 140 mg per mL, para-dichlorobenzene 20 mg per mL, chlorbutol 50 mg per mL, arachis oil 573 mg per mL, 10 mL, 1	‡1	..	..	14.42	6.10	Cerumol	UN
DOCUSATE								
4199B	docusate sodium 0.5% (5 mg/mL) ear drops, 10 mL	‡1	..	..	14.81	6.10	Waxsol	HM

VARIOUS

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VARIOUS

ALL OTHER THERAPEUTIC PRODUCTS

ALL OTHER THERAPEUTIC PRODUCTS

Drugs for treatment of hyperkalemia and hyperphosphatemia

POLYSTYRENE SULFONATE SODIUM								
4470G	polystyrene sulfonate sodium 999.3 mg/g powder, 454 g	#1	2	..	71.46	6.10	Resonium-A	SW

VARIOUS

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REPATRIATION PHARMACEUTICAL BENEFITS SCHEME (RPBS) WOUND ASSESSMENT AND DRESSING IDENTIFICATION

It is essential to define the aetiology of the wound before selecting a dressing. Recommendations are based on wound type, colour of wound base, depth of wound, and amount of exudate.

This wound chart adheres to the MOIST WOUND concept of healing and wound dressings are described below as ABSORBING or MOISTURE DONATING.

Most wound healing products are designed to remain in situ for several days, with the exception of those for infected wounds which should be changed daily. The quantities and repeats listed in the Repatriation Schedule are considered to be adequate to manage the treatment of a wound for two weeks to one month, when an assessment of the wound's healing process should be undertaken.

DRESSINGS

PINK EPITHELIALISING WOUND

Aim: To protect and promote epithelialisation. Epithelialising wounds normally are superficial and only produce a light exudate.

(A) Covering	- Film; - Film Island	- Gauze—Paraffin; - Non-adherent
(B) Absorbing	- Foam (Light Exudate); - Hydroactive (Superficial Wound—Light Exudate)	Hydrocolloid (Superficial Wound—Light Exudate)

RED GRANULATING WOUND

Aims: (1) to protect the granulating tissue; (2) to encourage epithelialisation; (3) to absorb excess exudate.

LIGHT EXUDATE:	Superficial	Cavity
(A) Absorbing	- Foam (Light Exudate); - Hydroactive (Superficial Wound—Light Exudate); - Hydrocolloid (Superficial Wound—Light Exudate)	Hydrocolloid (Cavity Wound)
(B) Moisture donating	- Hydrogel—Amorphous; - Hydrogel—Sheet	Hydrogel—Amorphous
HIGH EXUDATE:	Superficial	Cavity
(A) Absorbing	- Alginate (Superficial Wound); - Foam—Heavy Exudate; - Hydroactive (Superficial Wound—Moderate Exudate); - Hydrocolloid (Superficial Wound—Moderate/High Exudate)	- Alginate (Cavity Wound); - Foam—Moderate Exudate (see “cavity conforming” product); - Hydroactive (Cavity Wound); - Hydrocolloid (Cavity Wound)
(B) Moisture donating	NOT APPROPRIATE	

VARIOUS

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YELLOW SLOUGHY WOUND

Aims: (1) to remove slough; (2) to encourage granulation; (3) to absorb excess exudate.

LIGHT EXUDATE:	Superficial					Cavity	
(A) Absorbing	• Cadexomer Iodine; • Foam—Light Exudate; • Foam with Charcoal; • Hydroactive (Superficial Wound—Moderate Exudate); • Hydrocolloid (Superficial Wound—Moderate Exudate)					• Cadexomer Iodine; • Hydrocolloid (Cavity Wound)	
(B) Moisture Donating	• Hydrogel—Amorphous; • Hydrogel—Sheet					• Hydrogel—Amorphous	
HIGH EXUDATE:	Superficial					Cavity	
(A) Absorbing	• Alginate (Superficial Wound); • Cadexomer Iodine; • Foam—Heavy Exudate; • Hydroactive (Superficial Wound—Moderate/High Exudate); • Hydrocolloid (Superficial Wound—Moderate/High Exudate)					• Alginate (Cavity Wound); • Cadexomer Iodine; • Hydrocolloid (Cavity Wound)	
(B) Moisture donating	NOT APPROPRIATE						

BLACK NECROTIC WOUND

Aim: To remove eschar by — (1) sharp debridement, e.g., scissor/scalpel and/or (2) rehydration and autolytic debridement. (These wounds usually produce a LIGHT EXUDATE.)

DRY / LIGHT EXUDATE:	Superficial					Cavity	
(A) Absorbing	• Hydroactive (Superficial Wound—Light Exudate); • Hydrocolloid (Superficial Wound—Light/Moderate Exudate)					• Hydrocolloid (Cavity Wound)	
(B) Moisture donating	• Hydrogel—Amorphous; • Hydrogel—Sheet					• Hydrogel—Amorphous; • Hydrogel—Sheet	

INFECTED WOUNDS

Aims: (1) to clear the infection with systemic antibiotics; (2) to absorb excess exudate; (3) to remove slough if present; (4) to decrease bacterial burden - by applying a Silver dressing or Cadexomer Iodine dressing.

MALODOROUS WOUNDS

Aims: (1) to clear infection if present; (2) to remove slough if present; (3) to clear colonising odour-producing bacteria in slough — by applying metronidazole gel, a Silver dressing or a Cadexomer Iodine dressing; (4) to absorb excess exudate.

Products: Activated Charcoal; Alginate with Charcoal; Foam with Charcoal; Silver dressing; Cadexomer Iodine dressing.

MINOR SKIN TRAUMA

Aims: (1) to stop bleeding; (2) to prevent infection; (3) to minimise the surface defect; (4) to promote epithelialisation.

VARIOUS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer

ORDERING HARTMANN PRODUCTS

Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

ORDERING COLOPLAST PRODUCTS

Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

ORDERING MOLNLYCKE HEALTHCARE PRODUCTS

Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

ALL OTHER NON-THERAPEUTIC PRODUCTS

ALL OTHER NON-THERAPEUTIC PRODUCTS

LUBRICATING AGENT

4306P	lubricating agent jelly, 100 g	1	..	..	10.47	6.10	Lubri-Gel	PP

Other non-therapeutic auxiliary products

BANDAGE ABSORBENT WOOL

4653X	bandage absorbent wool 10 cm x 3 m bandage, 1	1	..	..	20.66	6.10	Surepress 650948	CC

BANDAGE CALICO

Note

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

4717G	bandage calico large bandage: triangular, 1 bandage	±1	..	..	13.38	6.10	Handy 36361414	BV

BANDAGE COMPRESSION

Note

Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

Note

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

4654Y	BANDAGE-COMPRESSION Bandage, short stretch, 8 cm x 2.6 m, 1	5	..	..	*76.11	6.10	Comprilan 01027-00	BV
4748X	bandage compression 10 cm x 3 m bandage: high stretch, 1 bandage	5	..	..	*73.26	6.10	Surepress 650947	CC
				..	*152.96	6.10	Tensopress 71723-00	BV

BANDAGE COMPRESSION

Note

Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

Note

Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

4657D	bandage compression 10 cm x 3.5 m bandage: high stretch, 1 bandage	5	..	..	*78.91	6.10	Setopress 3505	MH

BANDAGE COMPRESSION

Note

Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

VARIOUS

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Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.							
4598B	bandage compression bandage: four layer, 1 bandage	5	..	..	*160.01	6.10	Profore Lite 66050415 SN
4658E	bandage compression bandage: four layer, 1 bandage	5	..	..	*234.36	6.10	Profore 66050016 SN
BANDAGE COMPRESSION							
<u>Restricted benefit</u> Initial treatment of venous ulcers							
<u>Restricted benefit</u> Continuation of treatment of venous ulcers where patient's ability to tolerate dressing has been demonstrated							
Note Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.							
Note Bandage can be left in situ for up to 7 days as per manufacturer's instructions.							
4050E	bandage compression bandage: two layer, 1 bandage	1	..	..	43.02	6.10	Coban 2 MM
BANDAGE RETENTION COHESIVE HEAVY							
4813H	bandage retention cohesive heavy 10 cm x 1.3 m bandage, 1	2	..	..	*21.42	6.10	Peg 7423 MM
4660G	bandage retention cohesive heavy 10 cm x 2 m bandage, 1	2	..	..	*19.70	6.10	Coban 1584 MM
4814J	bandage retention cohesive heavy 15 cm x 1.3 m bandage, 1	2	..	..	*28.52	6.10	Peg 7425 MM
4811F	bandage retention cohesive heavy 5 cm x 1.3 m bandage, 1	2	..	..	*14.36	6.10	Peg 7420 MM
4812G	bandage retention cohesive heavy 7.5 cm x 1.3 m bandage, 1	2	..	..	*17.64	6.10	Peg 7422 MM
BANDAGE RETENTION COHESIVE LIGHT							
Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.							
4662J	bandage retention cohesive light 10 cm x 2 m bandage, 1	2	..	..	*31.42	6.10	Handygauze Cohesive 8635 BV
4718H	bandage retention cohesive light 2.5 cm x 2 m bandage, 2	#1	..	..	13.52	6.10	Handygauze Cohesive 8631 BV
4719J	bandage retention cohesive light 6 cm x 2 m bandage, 1	2	..	..	*16.14	6.10	Handygauze Cohesive 8633 BV
BANDAGE RETENTION COTTON CREPE							
Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.							
4729X	bandage retention cotton crepe 10 cm x 2.3 m bandage, 1	2	..	..	*25.72	6.10	Telfa 8254F KE
4727T	bandage retention cotton crepe 5 cm x 2.3 m bandage, 1	2	..	..	*30.92 *17.76	6.10 6.10	Tensocrepe 36301001 Telfa 8252F BV KE
4728W	bandage retention cotton crepe 7.5 cm x 2.3 m bandage, 1	2	..	..	*20.22 *22.56	6.10 6.10	Tensocrepe 36300501 Telfa 8253F BV KE
				..	*25.22	6.10	Tensocrepe 36307501 BV
BANDAGE TUBULAR							
Note Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed							

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prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.								
4859R	bandage tubular 10 cm x 1 m bandage, 1	‡1	..	..	15.32	6.10	Tubigrip F 1548	MH
4855M	bandage tubular 6.25 cm x 1 m bandage, 1	‡1	..	..	15.32	6.10	Tubigrip B 1520	MH
4856N	bandage tubular 6.75 cm x 1 m bandage, 1	‡1	..	..	15.32	6.10	Tubigrip C 1545	MH
4857P	bandage tubular 7.5 cm x 1 m bandage, 1	‡1	..	..	15.32	6.10	Tubigrip D 1546	MH
4858Q	bandage tubular 8.75 cm x 1 m bandage, 1	‡1	..	..	15.32	6.10	Tubigrip E 1547	MH
BANDAGE TUBULAR								
4663K	bandage tubular size C (15 cm to 25 cm) bandage: straight, 1 bandage	‡1	..	..	15.73	6.10	Elastoplast 2225	BE
4664L	bandage tubular size D (25 cm to 43 cm) bandage: straight, 1 bandage	‡1	..	..	15.73	6.10	Elastoplast 2226	BE
4665M	bandage tubular size E (35 cm to 45 cm) bandage: straight, 1 bandage	‡1	..	..	15.73	6.10	Elastoplast 2227	BE
BANDAGE TUBULAR FINGER								
4798M	BANDAGE-TUBULAR (FINGER) Complete pack including applicator, 1	‡1	..	..	18.11	6.10	Tubegauz 0501633	SS
BANDAGE TUBULAR LIGHT WEIGHT								
Note Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.								
4673Y	bandage tubular light weight 10 m bandage: large limb size, 1 bandage	‡1	..	..	28.47	6.10	Tubifast 2438	MH
4672X	bandage tubular light weight 10 m bandage: medium limb size, 1 bandage	‡1	..	..	27.06	6.10	Tubifast 2436	MH
4671W	bandage tubular light weight 10 m bandage: small limb size, 1 bandage	‡1	..	..	23.10	6.10	Tubifast 2434	MH
BANDAGE TUBULAR LONG STOCKING								
Note Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.								
4675C	bandage tubular long stocking bandage: XX/large size, 1 bandage	2	..	..	*37.48	6.10	Tubigrip 1486	MH
4799N	bandage tubular long stocking bandage: large size, 1 bandage	2	..	..	*37.46	6.10	Tubigrip 1484	MH
4797L	bandage tubular long stocking bandage: medium size, 1 bandage	2	..	..	*37.46	6.10	Tubigrip 1483	MH
4674B	bandage tubular long stocking bandage: small size, 1 bandage	2	..	..	*37.46	6.10	Tubigrip 1482	MH
BANDAGE TUBULAR SHORT STOCKING								
Note Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.								
4816L	bandage tubular short stocking bandage: large D/E size, 1 bandage	2	..	..	*25.72	6.10	Tubigrip 1481	MH
4815K	bandage tubular short stocking bandage: medium C/D size, 1 bandage	2	..	..	*25.72	6.10	Tubigrip 1480	MH

VARIOUS

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4661H	bandage tubular short stocking bandage: small B/C size, 1 bandage	2	..	..	*25.72	6.10	Tubigrip 1479	MH
BANDAGE ZINC PASTE								
Note Used as an adjunct in the management of leg ulceration and associated eczema and skin conditions.								
4670T	bandage zinc paste 10 cm x 9.1 m bandage, 1	2	3	..	*29.12	6.10	Flexidress 650941	CC
BANDAGE ZINC PASTE								
Note Used as an adjunct in the management of leg ulceration and associated eczema and skin conditions.								
Note Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.								
4669R	bandage zinc paste 7.5 cm x 6 m bandage, 1	2	3	..	*30.00	6.10	Steripaste 3610	MH
BANDAGE ZINC PASTE								
Note Used as an adjunct in the management of leg ulceration and associated eczema and skin conditions.								
Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.								
4750B	bandage zinc paste 7.5 cm x 6 m bandage, 1	2	3	..	*79.12	6.10	Viscopaste 4948	SN
4760M	bandage zinc paste 80 cm (stockings) bandage, 4	1	3	..	91.26	6.10	ZipZoc 66000747	SN
BETAINE + POLYAMINOPROPYL BIGUANIDE								
2525X	betaine 0.1% (40 microgram/40 mL) + polyaminopropyl biguanide 0.1% (40 microgram/40 mL), 6 x 40 mL ampoules	1	..	..	27.01	6.10	Prontosan Wound Irrigation Solution	BR
CADEXOMER-IODINE								
Note Suitable for yellow sloughy infected and malodorous wounds.								
Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.								
4937W	DRESSING with CADEXOMER IODINE Sheets 17 g (10 cm x 8 cm), 2, 1	1	..	..	163.92	6.10	Iodosorb 66051360	SN
4935R	DRESSING with CADEXOMER IODINE Sheets 5 g (6 cm x 4 cm), 5, 1	1	2	..	107.59	6.10	Iodosorb 66051330	SN
4931M	cadexomer-iodine 3 g powder: dusting sterile, 7 x 3 g sachets	1	2	..	70.65	6.10	Iodosorb Powder 66051070	SN
4933P	cadexomer-iodine 50% (500 mg/g) ointment, 2 x 20 g tubes	1	2	..	112.77	6.10	Iodosorb Ointment 66051230	SN
4932N	cadexomer-iodine 50% (500 mg/g) ointment, 4 x 10 g tubes	1	2	..	113.83	6.10	Iodosorb Ointment 66051240	SN
4936T	cadexomer-iodine 8 cm x 6 cm dressing, 3 x 10 g sheets	1	2	..	155.54	6.10	Iodosorb 66051340	SN
DRESSING ACTIVATED CHARCOAL MALODOROUS WOUND								
4742N	dressing activated charcoal malodorous wound 10 cm x 10 cm dressing, 10	1	..	..	79.32	6.10	CarboFLEX 403202	CC
4681J	dressing activated charcoal malodorous wound 10.5 cm x 10.5 cm dressing, 1	10	..	..	*101.26	6.10	Actisorb Plus MAP105	KI

VARIOUS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
4743P	dressing activated charcoal malodorous wound 15 cm x 20 cm dressing, 5	‡1	..	..	90.21	6.10	CarboFLEX 403204	CC
DRESSING ALGINATE CAVITY WOUND								
Note								
This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.								
4832H	DRESSING-ALGINATE (CAVITY WOUND) Rope 2 g, 1	10	..	..	*109.46	6.10	Sorbsan 1411	UM
1905G	DRESSING-ALGINATE (CAVITY WOUND) Rope 2 g, 5	2	..	..	*115.60	6.10	Kaltostat 168117	CC
DRESSING ALGINATE CAVITY WOUND								
Note								
This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.								
Note								
Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.								
4682K	dressing alginate cavity wound 2 g (40 cm) rope, 6 x 2 g	2	..	..	*138.06	6.10	Comfeel SeaSorb Filler 3740	CT
DRESSING ALGINATE SUPERFICIAL WOUND								
Note								
This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.								
Note								
Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.								
4831G	dressing alginate superficial wound 10 cm x 10 cm dressing, 1	10	1	..	*84.76	6.10	Sorbsan 1410	UM
				..	*90.46	6.10	Comfeel SeaSorb Dressing 3710	CT
4684M	dressing alginate superficial wound 5 cm x 5 cm dressing, 1	10	1	..	*47.26	6.10	Comfeel SeaSorb Dressing 3705	CT
DRESSING ALGINATE SUPERFICIAL WOUND								
Note								
This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.								
Note								
Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.								
4700J	dressing alginate superficial wound 10 cm x 10 cm dressing, 10	‡1	1	..	105.49	6.10	Algisite M 66000520	SN
4691X	dressing alginate superficial wound 15 cm x 20 cm dressing, 10	‡1	1	..	251.87	6.10	Algisite M 66000521	SN
4699H	dressing alginate superficial wound 5 cm x 5 cm dressing, 10	‡1	1	..	49.74	6.10	Kaltostat 168210	CC
				..	54.57	6.10	Algisite M 66000519	SN
DRESSING ALGINATE SUPERFICIAL WOUND								
Note								
This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.								
4683L	dressing alginate superficial wound 7.5 cm x 12 cm dressing, 10	‡1	1	..	91.42	6.10	Kaltostat 168212	CC
DRESSING FILM								
Note								
Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.								
4893M	dressing film 10 cm x 12 cm dressing, 10	‡1	..	..	34.08	6.10	Op-Site Flexigrid 4629	SN

VARIOUS

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DRESSING FILM								
4687Q	dressing film 10 cm x 12 cm dressing, 4	‡1	..	..	19.99	6.10	Nexcare Tegaderm Transparent H1626	MM
4688R	dressing film 15 cm x 20 cm dressing, 1	6	..	..	*31.00	6.10	Tegaderm Transparent 1628	MM
4686P	dressing film 6 cm x 7 cm dressing, 8	‡1	..	..	15.98	6.10	Nexcare Tegaderm Transparent H1624	MM
DRESSING FILM ISLAND								
4689T	dressing film island 5 cm x 7 cm dressing, 1	10	..	..	*16.56	6.10	Tegaderm Transparent Island 3582	MM
4690W	dressing film island 9 cm x 10 cm dressing, 1	10	..	..	*28.06	6.10	Tegaderm Transparent Island 3586	MM
DRESSING FILM ISLAND								
Note								
Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.								
4898T	dressing film island 5 cm x 7.2 cm dressing, 5	2	..	..	*29.32	6.10	Cutifilm Plus 36361370	SN
4899W	dressing film island 8 cm x 10 cm dressing, 5	2	..	..	*45.92	6.10	Cutifilm Plus 36361371	SN
DRESSING FOAM HEAVY EXUDATE								
Note								
This dressing should remain in place until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound.								
Note								
Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.								
4795J	dressing foam heavy exudate 10 cm x 10 cm dressing, 10	‡1	1	..	132.80	6.10	Allevyn 66007637	SN
DRESSING FOAM MODERATE EXUDATE								
Note								
This dressing should remain in place until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound.								
Note								
Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.								
4590N	dressing foam moderate exudate 12.5 cm x 12.5 cm dressing, 10	‡1	..	..	132.11	6.10	Allevyn Adhesive 66000044	SN
DRESSING FOAM MODERATE EXUDATE								
Note								
Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.								
4694C	dressing foam moderate exudate cavity conforming foam, 1 x 20 g sachet	1	1	..	95.09	6.10	Cavicare 4563	SN
DRESSING FOAM WITH SILICONE								
Note								
Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.								
10017F	dressing foam with silicone 10.3 cm x 10.3 cm dressing, 10	‡1	..	..	55.40	6.10	Allevyn Life 66801067	SN
10029W	dressing foam with silicone 12.9 cm x 12.9 cm dressing, 10	‡1	..	..	79.61	6.10	Allevyn Life 66801068	SN

VARIOUS

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10023M	dressings foam with silicone 15.4 cm x 15.4 cm dressing, 10	‡1	..	..	110.59	6.10	Allevyn Life 66801069	SN
10021K	dressings foam with silicone 21 cm x 21 cm dressing, 10	‡1	..	..	220.75	6.10	Allevyn Life 66801070	SN

DRESSING FOAM WITH SILICONE AND SILVER

Authority required

Wound critical colonisation or chronic wounds that have not responded to conventional dressings

Clinical criteria:

Patient must have a wound where there is evidence of critical colonisation; OR

Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

Note

Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

2439J	dressings foam with silicone and silver 10 cm x 10 cm dressing, 5	‡1	..	..	109.64	6.10	Mepilex Ag	MH
2470B	dressings foam with silicone and silver 10 cm x 10 cm dressing, 5	‡1	..	..	117.40	6.10	Mepilex Border Ag	MH

DRESSING FOAM WITH SILICONE HEAVY EXUDATE

Note

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

4196W	dressings foam with silicone heavy exudate 10 cm x 10 cm dressing, 10	‡1	..	..	73.50	6.10	Allevyn Gentle 66800248	SN
4230P	dressings foam with silicone heavy exudate 10 cm x 10 cm dressing, 10	‡1	..	..	73.50	6.10	Allevyn Gentle Border 66800270	SN
4207K	dressings foam with silicone heavy exudate 7.5 cm x 7.5 cm dressing, 10	‡1	..	..	51.71	6.10	Allevyn Gentle Border 66800269	SN

DRESSING FOAM WITH SILICONE HEAVY EXUDATE

Note

Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

4643J	dressings foam with silicone heavy exudate 10 cm x 10 cm dressing, 5	‡1	..	..	43.02	6.10	Mepilex Border 295300	MH
4642H	dressings foam with silicone heavy exudate 7.5 cm x 7.5 cm dressing, 5	‡1	..	..	31.11	6.10	Mepilex Border 295200	MH

DRESSING FOAM WITH SILICONE LIGHT EXUDATE

Note

Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

4645L	dressings foam with silicone light exudate 10 cm x 10 cm dressing, 5	‡1	..	..	38.55	6.10	Mepilex Lite 284100	MH
4644K	dressings foam with silicone light exudate 6 cm x 8.5 cm dressing, 5	‡1	..	..	28.40	6.10	Mepilex Lite 284000	MH

DRESSING FOAM WITH SILICONE MODERATE EXUDATE

Note

Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

4626L	dressings foam with silicone moderate exudate 10 cm x 10 cm dressing, 5	‡1	..	..	43.02	6.10	Mepilex 294100	MH

VARIOUS

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DRESSING FOAM WITH SILVER								
<u>Authority required</u>								
For wounds where there is evidence of critical colonisation and for well-assessed chronic wounds that have not responded to conventional dressings								
<u>Note</u>								
Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.								
4255Y	dressing foam with silver 10 cm x 10 cm dressing, 10	‡1	..	..	201.94	6.10	Allevyn Ag Adhesive 66800075	SN
4259E	dressing foam with silver 10 cm x 10 cm dressing, 10	‡1	..	..	205.72	6.10	Allevyn Ag Non-Adhesive 66800086	SN
4266M	dressing foam with silver 10 cm x 10 cm dressing, 10	‡1	..	..	201.94	6.10	Allevyn Ag Gentle Border 66800461	SN
4258D	dressing foam with silver 12.5 cm x 12.5 cm dressing, 10	‡1	..	..	246.56	6.10	Allevyn Ag Adhesive 66800078	SN
4270R	dressing foam with silver 12.5 cm x 12.5 cm dressing, 10	‡1	..	..	246.56	6.10	Allevyn Ag Gentle Border 66800462	SN
4252T	dressing foam with silver 7.5 cm x 7.5 cm dressing, 10	‡1	..	..	135.91	6.10	Allevyn Ag Adhesive 66800073	SN
4263J	dressing foam with silver 7.5 cm x 7.5 cm dressing, 10	‡1	..	..	135.91	6.10	Allevyn Ag Gentle Border 66800460	SN
DRESSING GAUZE ABSORBENT								
<u>Note</u>								
Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.								
4708T	dressing gauze absorbent 10 cm x 10 cm pad, 100	‡1	..	..	30.25	6.10	Handy 71117-06	BV
4707R	dressing gauze absorbent 5 cm x 5 cm pad, 100	‡1	..	..	15.13	6.10	Handy 71117-05	BV
DRESSING GAUZE EYE								
4768Y	dressing gauze eye pad, 12	‡1	..	..	13.17	6.10	Curity 4112	KE
DRESSING GAUZE PARAFFIN								
<u>Note</u>								
Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.								
4759L	dressing gauze paraffin 10 cm x 10 cm dressing, 10	‡1	..	..	21.26	6.10	Jelonet 7404	SN
DRESSING GAUZE PARAFFIN WITH CHLORHEXIDINE ACETATE								
<u>Note</u>								
Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.								
4845B	dressing gauze paraffin with chlorhexidine acetate 10 cm x 10 cm dressing, 10	‡1	2	..	24.65	6.10	Bactigras 7457	SN
DRESSING HYDROACTIVE CAVITY WOUND								
<u>Note</u>								
Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.								
4919X	dressing hydroactive cavity wound 10 cm x 10 cm dressing, 5	2	1	..	*200.48	6.10	Allevyn Plus Cavity 66047573	SN
4918W	dressing hydroactive cavity wound 5 cm x 6 cm dressing, 10	‡1	1	..	94.84	6.10	Allevyn Plus Cavity 66047571	SN

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DRESSING HYDROACTIVE DEBRIDEMENT								
Note								
Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.								
4949L	DRESSING-HYDROACTIVE (DEBRIDEMENT) Dressings 4 cm, 10, 1	‡1	..	..	85.22	6.10	TenderWet 24 Active 609210	HR
4948K	DRESSING-HYDROACTIVE (DEBRIDEMENT) Dressings 5.5 cm, 10, 1	‡1	..	..	87.27	6.10	TenderWet Active Cavity 609272	HR
4950M	DRESSING-HYDROACTIVE (DEBRIDEMENT) Dressings 7.5 cm x 7.5 cm, 10, 1	‡1	..	..	115.58	6.10	TenderWet 24 Active 609213	HR
DRESSING HYDROACTIVE SUPERFICIAL WOUND HIGH EXUDATE SEMI-PERMEABLE ABSORBENT FOAM								
4692Y	dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 10 cm x 10 cm (foam alternative) dressing, 10	‡1	..	..	55.24	6.10	CombiDERM 651031	CC
4695D	dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 11 cm x 11 cm dressing: island, 10 dressings	‡1	..	..	111.58	6.10	Tielle MTL101E	KI
4693B	dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 15 cm x 18 cm (foam alternative) dressing, 5	‡1	..	..	72.06	6.10	CombiDERM 651027	CC
4696E	dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 18 cm x 18 cm dressing: island, 5 dressings	‡1	..	..	136.18	6.10	Tielle MT2442	KI
DRESSING HYDROACTIVE SUPERFICIAL WOUND HIGH EXUDATE SEMI-PERMEABLE ABSORBENT FOAM								
Note								
Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.								
4927H	dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 10 cm x 10 cm pad: waterproof, 10 pads	‡1	1	..	88.27	6.10	Biatain Non-adhesive 3410	CT
4929K	dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 12 cm x 12 cm pad: waterproof, 10 pads	‡1	1	..	97.29	6.10	Biatain Adhesive 3420	CT
4928J	dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 15 cm x 15 cm pad: waterproof, 5 pads	‡1	2	..	86.79	6.10	Biatain Non-adhesive 3413	CT
4930L	dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 18 cm x 18 cm pad: waterproof, 5 pads	‡1	2	..	94.16	6.10	Biatain Adhesive 3423	CT
DRESSING HYDROACTIVE SUPERFICIAL WOUND LIGHT EXUDATE								
Note								
Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.								
4906F	dressing hydroactive superficial wound light exudate 10 cm x 10 cm dressing, 5	2	1	..	*113.60	6.10	Allevyn Thin 66047578	SN
4905E	dressing hydroactive superficial wound light exudate 5 cm x 6 cm dressing, 10	‡1	1	..	62.07	6.10	Allevyn Thin 66047576	SN

DRESSING HYDROACTIVE SUPERFICIAL WOUND MODERATE EXUDATE

Note

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed

DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE

Note
This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

Note

VARIOUS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.								
4923D	DRESSING-HYDROCOLLOID (SUPERFICIAL WOUND-MODERATE EXUDATE) Dressings with alginate 10 cm x 10 cm, 10, 1	1	1	..	82.34	6.10	Comfeel Plus Ulcer Dressing 3110	CT
4679G	dressing hydrocolloid superficial wound moderate exudate 10 cm (round) dressing, 1	5	..	..	*59.96	6.10	Comfeel Plus Pressure Relieving 3353	CT
4678F	dressing hydrocolloid superficial wound moderate exudate 7 cm (butterfly shape) dressing, 1	5	..	..	*55.51	6.10	Comfeel Plus Pressure Relieving 3350	CT
DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE								
Note								
This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.								
Note								
Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.								
4921B	dressing hydrocolloid superficial wound moderate exudate 10 cm x 10 cm dressing, 10	1	1	..	86.04	6.10	Replicare Ultra 66000434	SN
DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE								
Note								
This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.								
Note								
Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.								
4945G	dressing hydrocolloid superficial wound moderate exudate 10 cm x 10 cm dressing, 10	1	1	..	48.49	6.10	Hydrocoll 900744	HR
4946H	dressing hydrocolloid superficial wound moderate exudate 15 cm x 15 cm dressing, 10	1	1	..	90.25	6.10	Hydrocoll 900936	HR
DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE								
Note								
This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.								
4897R	dressing hydrocolloid superficial wound moderate exudate 10 cm x 10 cm dressing, 5	2	1	..	*81.74	6.10	DuoDERM CGF H7660	CC
4920Y	dressing hydrocolloid superficial wound moderate exudate 20 cm x 20 cm dressing, 5	2	1	..	*222.66	6.10	DuoDERM CGF H7662	CC
DRESSING HYDROFIBRE ALTERNATE TO ALGINATES								
2797F	dressing hydrofibre alternate to alginates 10 cm x 10 cm dressing, 10	1	1	..	101.32	6.10	Aquacel Extra 420672	CC
2803M	dressing hydrofibre alternate to alginates 15 cm x 15 cm dressing, 5	2	1	..	*209.04	6.10	Aquacel Extra 420673	CC
4698G	dressing hydrofibre alternate to alginates 2 g (30 cm) rope, 5 x 2 g	1	1	..	84.05	6.10	Aquacel 403770	CC
DRESSING HYDROFIBRE GELLING FIBRE								
Note								
Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.								
2486W	dressing hydrofibre gelling fibre 10 cm x 10 cm dressing, 10	1	1	..	95.82	6.10	Durafiber 66800560	SN
2445Q	dressing hydrofibre gelling fibre 15 cm x 15 cm dressing, 5	2	1	..	*199.16	6.10	Durafiber 66800561	SN
2462N	dressing hydrofibre gelling fibre 2 cm x	1	1	..	80.04	6.10	Durafiber 66800563	SN

VARIOUS

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	45 cm rope, 5							
	DRESSING HYDROFIBRE WITH SILVER							
	Authority required							
	Wound critical colonisation or chronic wounds that have not responded to conventional dressings							
	Clinical criteria:							
	Patient must have a wound where there is evidence of critical colonisation; OR							
	Patient must have a well-assessed chronic wound that has not responded to conventional dressings.							
10097K	dressing hydrofibre with silver 10 cm x 10 cm dressing, 10	‡1	1	..	262.40	6.10	Aquacel Ag 403708	CC
10098L	dressing hydrofibre with silver 15 cm x 15 cm dressing, 5	‡1	1	..	279.45	6.10	Aquacel Ag 403710	CC
10105W	dressing hydrofibre with silver 2 cm x 45 cm rope, 5	‡1	1	..	224.78	6.10	Aquacel Ag 403771	CC
	DRESSING HYDROGEL							
2471C	dressing hydrogel 10 cm x 10 cm dressing, 20	1	..	..	114.38	6.10	Sorbact Absorption Dressing S98222	QL
	DRESSING HYDROGEL AMORPHOUS							
	Note							
	This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.							
	Note							
	Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.							
4912M	dressing hydrogel amorphous gel, 10 x 15 g tubes	‡1	1	..	64.82	6.10	DuoDERM Gel H7990	CC
				..	72.43	6.10	Comfeel Purilon Gel 3900	CT
	DRESSING HYDROGEL AMORPHOUS							
	Note							
	This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.							
	Note							
	Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.							
4894N	dressing hydrogel amorphous gel, 25 g	4	3	..	*66.56	6.10	Intrasite Gel 7313	SN
4599C	dressing hydrogel amorphous gel, 50 g	3	3	..	*31.57	6.10	SoloSite Gel 36361338	SN
	DRESSING HYDROGEL AMORPHOUS							
	Note							
	This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.							
4913N	dressing hydrogel amorphous gel, 3 x 30 g tubes	3	1	..	*97.45	6.10	DuoDERM Gel H7987	CC
4914P	dressing hydrogel amorphous gel, 50 g	3	3	..	*33.46	6.10	Solugel 10336	JJ
	DRESSING HYDROGEL FOAM							
2533H	dressing hydrogel foam 10 cm x 10 cm dressing, 10	1	..	..	79.79	6.10	Sorbact Foam Dressing S98310	QL
	DRESSING HYDROGEL RIBBON							
2512F	dressing hydrogel ribbon 1 cm x 50 cm dressing, 20	1	..	..	118.23	6.10	Sorbact Ribbon Gauze S98118	QL
2529D	dressing hydrogel ribbon 5 cm x 200 cm dressing, 10	1	..	..	114.38	6.10	Sorbact Ribbon Gauze S98120	QL

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
DRESSING HYDROGEL SHEET								
Note This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.								
Note Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.								
4806Y	dressing hydrogel sheet 10 cm x 10 cm dressing, 5	2	..	..	*53.62	6.10	Hydrosorb 900854	HR
DRESSING HYDROGEL SHEET								
Note This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.								
4911L	dressing hydrogel sheet 9.5 cm x 10.2 cm dressing, 5	2	..	..	*83.54	6.10	Nu-Gel 2497	KI
DRESSING NON ADHERENT								
Note Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.								
4243H	DRESSING SELF ADHESIVE NON-ADHERENT DRY ABSORBENT Dressings, non-woven, with silicone 5 cm x 7.5 cm, 10, 1	‡1	..	..	63.96	6.10	Mepitel 290510	MH
4244J	DRESSING SELF ADHESIVE NON-ADHERENT DRY ABSORBENT Dressings, non-woven, with silicone 7.5 cm x 10 cm, 10, 1	‡1	..	..	107.96	6.10	Mepitel 290710	MH
DRESSING NON ADHERENT								
Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.								
4861W	dressing non adherent 10 cm x 10 cm dressing, 10	‡1	..	..	36.03	6.10	Melolin 66974933	SN
4862X	dressing non adherent 10 cm x 10 cm dressing, 5	2	..	..	*25.44	6.10	Cutilin Non-Stick Wound Pad 36361375	SN
4819P	dressing non adherent 5 cm x 5 cm dressing, 5	2	..	..	*15.96	6.10	Cutilin Non-Stick Wound Pad 36361374	SN
4860T	dressing non adherent 5 cm x 5 cm dressing, 5	2	..	..	*17.24	6.10	Melolin 36361357	SN
DRESSING NON ADHERENT								
4755G	dressing non adherent 5 cm x 7.5 cm dressing, 10	‡1	..	..	11.36	6.10	Telfa 1970C	KE
4758K	dressing non adherent 7.5 cm x 10 cm self adhesive dressing, 6	‡1	..	..	11.57	6.10	Telfa 2140C	KE
4844Y	dressing non adherent 7.5 cm x 10 cm self adhesive dressing, 6	‡1	2	..	12.36	6.10	Telfa 7650C	KE
DRESSING NON ADHERENT								
Note Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.								
4944F	dressing non adherent 7.5 cm x 10 cm dressing, 10	‡1	..	..	15.58	6.10	Atrauman 499513	HR
DRESSING TULLE NON GAUZE PARAFFIN								

VARIOUS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
4909J	dressing tulle non gauze paraffin 7.6 cm x 7.6 cm dressing, 1	10	1	..	*16.06	6.10	Adaptic 2012	KI

DRESSING WITH SILVER

Authority required

For wounds where there is evidence of critical colonisation and for well-assessed chronic wounds that have not responded to conventional dressings

Note

Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

4646M	dressing with silver 10 cm x 10 cm dressing: hydroactive, 5 dressings	1	..	..	176.22	6.10	Biatain Ag 9622	CT
4647N	dressing with silver 12.5 cm x 12.5 cm dressing: hydroactive, 5 dressings	1	..	..	191.63	6.10	Biatain Ag 9632	CT

DRESSING WITH SILVER

Authority required

For wounds where there is evidence of critical colonisation and for well-assessed chronic wounds that have not responded to conventional dressings

Note

Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

4648P	dressing with silver 10 cm x 10 cm dressing: tulle, 3 dressings	1	..	..	44.12	6.10	Atrauman Ag 499572	HR

GAUZE AND COTTON TISSUE COMBINE ROLL

4761N	gauze and cotton tissue combine roll 10 cm x 10 m roll: wrapped pack, 1 pack	1	..	..	17.55	6.10	JJ 12010	JJ

GAUZE AND COTTON TISSUE COMBINE ROLL

Note

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

4767X	gauze and cotton tissue combine roll 9 cm x 10 m roll: wrapped pack, 1 pack	1	..	..	11.92	6.10	BSN 2902165	BV

TAPE NON WOVEN RETENTION POLYACRYLATE

Note

Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

4917T	tape non woven retention polyacrylate 2.5 cm x 10 m tape, 1 roll	1	..	..	11.38	6.10	Mefix 310250	MH

TAPE NON WOVEN RETENTION POLYACRYLATE

4915Q	tape non woven retention polyacrylate 2.5 cm x 9.1 m tape, 1 roll	1	..	..	13.21	6.10	Medipore 2961	MM

TAPE PLASTER ADHESIVE ELASTIC

Note

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

4780N	tape plaster adhesive elastic 2.5 cm x 2.5 m tape, 1 roll	1	..	..	13.95	6.10	Leukoplast 01071-00	BV
4781P	tape plaster adhesive elastic 5 cm x 2.5 m tape, 1 roll	1	..	..	20.50	6.10	Leukoplast 01072-00	BV
4782Q	tape plaster adhesive elastic 7.5 cm x 2.5 m tape, 1 roll	1	..	..	24.55	6.10	Leukoplast 01073-00	BV

TAPE PLASTER ADHESIVE HYPOALLERGENIC

Note

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS

VARIOUS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.								
4783R	tape plaster adhesive hypoallergenic 1.25 cm x 5 m tape, 1 roll	‡1	..	..	11.10	6.10	Leukopor 2471	BV
4785W	tape plaster adhesive hypoallergenic 1.25 cm x 5 m tape, 1 roll	‡1	..	..	11.42	6.10	Leukosilk 1021	BV
4787Y	tape plaster adhesive hypoallergenic 2.5 cm x 5 m tape, 1 roll	‡1	..	..	14.34	6.10	Leukosilk 1022	BV
4794H	tape plaster adhesive hypoallergenic 2.5 cm x 5 m tape, 1 roll	‡1	..	..	13.76	6.10	Leukopor 2472	BV
4788B	tape plaster adhesive hypoallergenic 5 cm x 5 m stretch tape, 1 roll	‡1	..	..	17.55	6.10	Leukoflex 1124	BV
4789C	tape plaster adhesive hypoallergenic 5 cm x 5 m stretch tape, 1 roll	‡1	..	..	18.55	6.10	Leukosilk 1024	BV
4790D	tape plaster adhesive hypoallergenic 5 cm x 5 m stretch tape, 1 roll	‡1	..	..	17.63	6.10	Leukopor 2474	BV
TAPE PLASTER ADHESIVE HYPOALLERGENIC								
4848E	tape plaster adhesive hypoallergenic 1.9 cm x 5.4 m dispenser tape, 1 roll	‡1	..	..	11.39	6.10	Nexcare Durable Cloth First Aid Tape 799	MM
4849F	tape plaster adhesive hypoallergenic 1.9 cm x 7.3 m dispenser tape, 1 roll	‡1	..	..	11.39	6.10	Nexcare Gentle Paper First Aid Tape 789	MM
TAPE PLASTER ADHESIVE WITH SILICONE								
Note								
Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.								
4239D	tape plaster adhesive with silicone 2 cm x 3 m tape, 1 roll	‡1	..	..	21.71	6.10	Mepitac 298300	MH
4240E	tape plaster adhesive with silicone 4 cm x 1.5 m tape, 1 roll	‡1	..	..	21.71	6.10	Mepitac 298400	MH

Section 2

Standard Packs and Prices

NOTE—

Standard packs and prices (including mark-up, but without dispensing fee and dangerous drug fee) are for items against the price of which an asterisk () is shown in Section 1 of the Schedule.*

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name, Form/Strength	Pack and Price	Manufacturer
10031Y	alprostadil 10 microgram injection [1 x 10 microgram vial] (&) inert substance diluent [1 syringe], 1 pack	1@ 16.51	PF
10030X	alprostadil 20 microgram injection [1 x 20 microgram vial] (&) inert substance diluent [1 syringe], 1 pack	1@ 21.07	PF
4118R	ALUMINIUM HYDROXIDE with MAGNESIUM HYDROXIDE and SIMETHICONE Oral suspension 400 mg-400 mg-30 mg per 5 mL, 500 mL, 1	1@ 8.11	JT
4453J	ALUMINIUM HYDROXIDE with MAGNESIUM HYDROXIDE and SIMETHICONE Tablet 400 mg-400 mg-40 mg, 100	100@ 19.85	JT
4657D	bandage compression 10 cm x 3.5 m bandage: high stretch, 1 bandage	1@ 14.43	MH
4748X	bandage compression 10 cm x 3 m bandage: high stretch, 1 bandage	1@ 29.24	BV
4748X	bandage compression 10 cm x 3 m bandage: high stretch, 1 bandage	1@ 13.30	CC
4654Y	BANDAGE-COMPRESSION Bandage, short stretch, 8 cm x 2.6 m, 1	1@ 13.87	BV
4598B	bandage compression bandage: four layer, 1 bandage	1@ 30.65	SN
4658E		1@ 45.52	SN
4813H	bandage retention cohesive heavy 10 cm x 1.3 m bandage, 1	1@ 7.33	MM
4660G	bandage retention cohesive heavy 10 cm x 2 m bandage, 1	1@ 6.47	MM
4814J	bandage retention cohesive heavy 15 cm x 1.3 m bandage, 1	1@ 10.88	MM
4811F	bandage retention cohesive heavy 5 cm x 1.3 m bandage, 1	1@ 3.80	MM
4812G	bandage retention cohesive heavy 7.5 cm x 1.3 m bandage, 1	1@ 5.44	MM
4662J	bandage retention cohesive light 10 cm x 2 m bandage, 1	1@ 12.33	BV
4719J	bandage retention cohesive light 6 cm x 2 m bandage, 1	1@ 4.69	BV
4729X	bandage retention cotton crepe 10 cm x 2.3 m bandage, 1	1@ 12.08	BV
4729X	bandage retention cotton crepe 10 cm x 2.3 m bandage, 1	1@ 9.48	KE
4727T	bandage retention cotton crepe 5 cm x 2.3 m bandage, 1	1@ 5.50	KE
4727T	bandage retention cotton crepe 5 cm x 2.3 m bandage, 1	1@ 6.73	BV
4728W	bandage retention cotton crepe 7.5 cm x 2.3 m bandage, 1	1@ 9.23	BV
4728W	bandage retention cotton crepe 7.5 cm x 2.3 m bandage, 1	1@ 7.90	KE
4799N	bandage tubular long stocking bandage: large size, 1 bandage	1@ 15.35	MH
4797L	bandage tubular long stocking bandage: medium size, 1 bandage	1@ 15.35	MH
4674B	bandage tubular long stocking bandage: small size, 1 bandage	1@ 15.35	MH
4675C	bandage tubular long stocking bandage: XX/large size, 1 bandage	1@ 15.36	MH
4816L	bandage tubular short stocking bandage: large D/E size, 1 bandage	1@ 9.48	MH
4815K	bandage tubular short stocking bandage: medium C/D size, 1 bandage	1@ 9.48	MH
4661H	bandage tubular short stocking bandage: small B/C size, 1 bandage	1@ 9.48	MH
4670T	bandage zinc paste 10 cm x 9.1 m bandage, 1	1@ 11.18	CC
4669R	bandage zinc paste 7.5 cm x 6 m bandage, 1	1@ 11.62	MH
4750B		1@ 36.18	SN
4150K	bromazepam 3 mg tablet, 30	30@ 11.53	RO
4151L	bromazepam 6 mg tablet, 30	30@ 14.84	RO
4055K	calcium carbonate 420 mg + glycine 180 mg tablet: chewable, 100	100@ 8.38	MM
4094L	CALCIUM Tablet (chewable) 500 mg (as carbonate), 60	60@ 5.62	IA, PP
4333C		60@ 5.62	IA, PP
4142B	CALCIUM Tablet 600 mg (as carbonate), 120	120@ 7.89	PP
4681J	dressing activated charcoal malodorous wound 10.5 cm x 10.5 cm dressing, 1	1@ 9.45	KI
4832H	DRESSING-ALGINATE (CAVITY WOUND) Rope 2 g, 1	1@ 10.27	UM
1905G	DRESSING-ALGINATE (CAVITY WOUND) Rope 2 g, 5	5@ 54.42	CC
4682K	dressing alginate cavity wound 2 g (40 cm) rope, 6 x 2 g	1@ 65.65	CT
4831G	dressing alginate superficial wound 10 cm x 10 cm dressing, 1	1@ 7.80	UM
4831G	dressing alginate superficial wound 10 cm x 10 cm dressing, 1	1@ 8.37	CT
4684M	dressing alginate superficial wound 5 cm x 5 cm dressing, 1	1@ 4.05	CT
4688R	dressing film 15 cm x 20 cm dressing, 1	1@ 4.04	MM
4898T	dressing film island 5 cm x 7.2 cm dressing, 5	1@ 11.28	SN
4689T	dressing film island 5 cm x 7 cm dressing, 1	1@ 0.98	MM
4899W	dressing film island 8 cm x 10 cm dressing, 5	1@ 19.58	SN
4690W	dressing film island 9 cm x 10 cm dressing, 1	1@ 2.13	MM
4919X	dressing hydroactive cavity wound 10 cm x 10 cm dressing, 5	1@ 96.86	SN
4906F	dressing hydroactive superficial wound light exudate 10 cm x 10 cm dressing, 5	1@ 53.42	SN
4886E	dressing hydroactive superficial wound moderate exudate 10 cm x 10 cm dressing, 5	1@ 39.17	SN
4896Q	dressing hydrocolloid cavity wound paste, 30 g	1@ 13.87	CC
4895P	dressing hydrocolloid cavity wound paste, 50 g	1@ 18.40	CT
4679G	dressing hydrocolloid superficial wound moderate exudate 10 cm	1@ 10.64	CT

(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

Code	Name, Form/Strength	Pack and Price	Manufacturer
4897R	(round) dressing, 1 dressing hydrocolloid superficial wound moderate exudate 10 cm x 10 cm dressing, 5	1@ 37.49	CC
4920Y	dressing hydrocolloid superficial wound moderate exudate 20 cm x 20 cm dressing, 5	1@ 107.95	CC
4678F	dressing hydrocolloid superficial wound moderate exudate 7 cm (butterfly shape) dressing, 1	1@ 9.75	CT
2803M	dressing hydrofibre alternate to alginates 15 cm x 15 cm dressing, 5	1@ 101.14	CC
2445Q	dressing hydrofibre gelling fibre 15 cm x 15 cm dressing, 5	1@ 96.20	SN
4894N	dressing hydrogel amorphous gel, 25 g	1@ 14.95	SN
4913N	dressing hydrogel amorphous gel, 3 x 30 g tubes	1@ 30.23	CC
4599C	dressing hydrogel amorphous gel, 50 g	1@ 8.27	SN
4914P		1@ 8.90	JJ
4806Y	dressing hydrogel sheet 10 cm x 10 cm dressing, 5	1@ 23.43	HR
4911L	dressing hydrogel sheet 9.5 cm x 10.2 cm dressing, 5	1@ 38.39	KI
4862X	dressing non adherent 10 cm x 10 cm dressing, 5	1@ 9.34	SN
4819P	dressing non adherent 5 cm x 5 cm dressing, 5	1@ 4.60	SN
4860T		1@ 5.24	SN
4909J	dressing tulle non gauze paraffin 7.6 cm x 7.6 cm dressing, 1	1@ 0.93	KI
4237B	fexofenadine hydrochloride 60 mg tablet, 20	20@ 16.19	SW
4246L	glycerol 2.8 g suppository, 12	1@ 5.13	PP
4577X	nicotine 10 mg/16 hours patch, 7	1@ 24.18	JT
4572P	nicotine 14 mg/24 hours patch, 7	1@ 24.07	AF
4572P	nicotine 14 mg/24 hours patch, 7	1@ 31.16	GC
4578Y	nicotine 15 mg/16 hours patch, 7	1@ 26.77	JT
4573Q	nicotine 21 mg/24 hours patch, 7	1@ 31.16	GC
4573Q	nicotine 21 mg/24 hours patch, 7	1@ 25.63	AF
4576W	nicotine 5 mg/16 hours patch, 7	1@ 22.19	JT
4571N	nicotine 7 mg/24 hours patch, 7	1@ 22.49	AF

GENERIC/PROPRIETARY INDEX

GENERIC/PROPRIETARY INDEX

3

3TC (VI)
.Section 100 746, 1003

A

ABACAVIR
.Section 100 744, 1000

ABACAVIR + LAMIVUDINE
.Section 100 751, 1008

ABACAVIR + LAMIVUDINE + ZIDOVUDINE
.Section 100 751, 1008

ABATACEPT
.ANTINEOPLASTIC AND IMMUNOMODULATING
AGENTS 304, 311
.Section 100 780, 1039

Abbocillin-V (QA)
.ANTIINFECTIVES FOR SYSTEMIC USE 227

Abbocillin-VK Filmtab (QA)
.ANTIINFECTIVES FOR SYSTEMIC USE 227, 228

ABCIXIMAB
.BLOOD AND BLOOD FORMING ORGANS 105

Abilify (BQ)
.NERVOUS SYSTEM 555

Abilify Maintena (LU)
.NERVOUS SYSTEM 555

ABIRATERONE
.ANTINEOPLASTIC AND IMMUNOMODULATING
AGENTS 299

Abisart (AF)
.CARDIOVASCULAR SYSTEM 145

Abisart HCT 150/12.5 (AF)
.CARDIOVASCULAR SYSTEM 149

Abisart HCT 300/12.5 (AF)
.CARDIOVASCULAR SYSTEM 149

Abisart HCT 300/25 (AF)
.CARDIOVASCULAR SYSTEM 149

ACAMPROSATE
.NERVOUS SYSTEM 588

ACARBOSE
.ALIMENTARY TRACT AND METABOLISM 90

Accomin Adult Tonic (PF)
.Repatriation Schedule 1246

Accu-Chek Active (RD)
.VARIOUS 630, 631

Accu-Chek Advantage/Sensor Comfort (RD)
.VARIOUS 630, 631

Accu-Chek Aviva (RD)
.VARIOUS 630, 631

Accu-Chek Go (RD)
.VARIOUS 630, 631

Accu-Chek Integra (RD)

.VARIOUS 630, 631

Accu-Chek Mobile (RD)
.VARIOUS 632

Accu-Chek Performa (RD)
.VARIOUS 630, 631

Accupril (PF)
.CARDIOVASCULAR SYSTEM 138

Accuretic 10/12.5mg (PF)
.CARDIOVASCULAR SYSTEM 142

Accuretic 20/12.5mg (PF)
.CARDIOVASCULAR SYSTEM 142

ACETAZOLAMIDE
.SENSORY ORGANS 609

Acetec (AL)
.CARDIOVASCULAR SYSTEM 135

ACETIC ACID + HYDROXYQUINOLINE + RICINOLEIC ACID
.Repatriation Schedule 1256

ACICLOVIR
.ANTIINFECTIVES FOR SYSTEMIC USE 250, 251
.SENSORY ORGANS 606

Aciclovir 200 (CR)
.ANTIINFECTIVES FOR SYSTEMIC USE 250

Aciclovir 800 (CR)
.ANTIINFECTIVES FOR SYSTEMIC USE 251

Aciclovir GH (GQ)
.ANTIINFECTIVES FOR SYSTEMIC USE 250

Acihexal (SZ)
.ANTIINFECTIVES FOR SYSTEMIC USE 250, 251

Aci-Jel (CU)
.Repatriation Schedule 1256

Acimax Tablets (AL)
.ALIMENTARY TRACT AND METABOLISM 64

ACITRETIN
.DERMATOLOGICALS 194

Acitretin Actavis (GN)
.DERMATOLOGICALS 194

Aclasta (NV)
.MUSCULO-SKELETAL SYSTEM 501, 502

ACLIDINIUM
.RESPIRATORY SYSTEM 601

Aclor 125 (QA)
.ANTIINFECTIVES FOR SYSTEMIC USE 234

Aclor 250 (QA)
.ANTIINFECTIVES FOR SYSTEMIC USE 234

Acpio 15 (QA)
.ALIMENTARY TRACT AND METABOLISM 92

Acpio 30 (QA)
.ALIMENTARY TRACT AND METABOLISM 92

Acpio 45 (QA)
.ALIMENTARY TRACT AND METABOLISM 92

Acquin Aspen 10 (AS)
.CARDIOVASCULAR SYSTEM 138

Acquin Aspen 20 (AS)
.CARDIOVASCULAR SYSTEM 138

GENERIC/PROPRIETARY INDEX

<i>Acquin Aspen 5 (AS)</i>		
.CARDIOVASCULAR SYSTEM	138	
<i>Acris Combi (AF)</i>		
.MUSCULO-SKELETAL SYSTEM	505	
.Repatriation Schedule	1262	
<i>Acris Once-a-Month (AF)</i>		
.MUSCULO-SKELETAL SYSTEM	500	
<i>Acris Once-a-Week (AF)</i>		
.MUSCULO-SKELETAL SYSTEM	500	
.Repatriation Schedule	1261	
<i>Actemra (RO)</i>		
.Section 100	878, 886, 893, 903, 1136, 1144, 1145, 1151, 1161	
<i>Actilax (AF)</i>		
.ALIMENTARY TRACT AND METABOLISM	73	
.Palliative Care	663	
<i>Actiq (OA)</i>		
.Palliative Care	672, 673	
<i>Actisorb Plus MAP105 (KI)</i>		
.Repatriation Schedule	1276	
<i>Actonel (UA)</i>		
.MUSCULO-SKELETAL SYSTEM	500	
.Repatriation Schedule	1261	
<i>Actonel EC (UA)</i>		
.MUSCULO-SKELETAL SYSTEM	500	
.Repatriation Schedule	1261	
<i>Actonel EC Combi (UA)</i>		
.MUSCULO-SKELETAL SYSTEM	505	
.Repatriation Schedule	1262	
<i>Actonel EC Combi D (UA)</i>		
.MUSCULO-SKELETAL SYSTEM	506	
.Repatriation Schedule	1262	
<i>Actonel Once-a-Month (UA)</i>		
.MUSCULO-SKELETAL SYSTEM	500	
<i>Actos (TK)</i>		
.ALIMENTARY TRACT AND METABOLISM	92	
<i>Actrapid (NO)</i>		
.ALIMENTARY TRACT AND METABOLISM	82	
<i>Actrapid Penfill 3 mL (NO)</i>		
.ALIMENTARY TRACT AND METABOLISM	82	
<i>Acyclo-V 200 (AF)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE	250	
<i>Acyclo-V 800 (AF)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE	251	
<i>Adalat 10 (BN)</i>		
.CARDIOVASCULAR SYSTEM	133	
<i>Adalat 20 (BN)</i>		
.CARDIOVASCULAR SYSTEM	133	
<i>Adalat Oros 20mg (BN)</i>		
.CARDIOVASCULAR SYSTEM	133	
<i>Adalat Oros 30 (BN)</i>		
.CARDIOVASCULAR SYSTEM	133	
<i>Adalat Oros 60 (BN)</i>		
.CARDIOVASCULAR SYSTEM	133	
ADALIMUMAB		
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	317, 323, 326, 329, 332, 339, 342, 346, 349, 353, 356, 362, 367, 372	
.Section 100	803, 1062	
ADAPALENE + BENZOYL PEROXIDE		
.DERMATOLOGICALS	197	
<i>Adaptic 2012 (KI)</i>		
.Repatriation Schedule	1286	
<i>Adcirca (LY)</i>		
.Section 100	733, 988	
<i>add-ins (SB)</i>		
.VARIOUS	653	
<i>Addos XR 30 (QA)</i>		
.CARDIOVASCULAR SYSTEM	133	
<i>Addos XR 60 (QA)</i>		
.CARDIOVASCULAR SYSTEM	133	
<i>Adefin 10 (AF)</i>		
.CARDIOVASCULAR SYSTEM	133	
<i>Adefin 20 (AF)</i>		
.CARDIOVASCULAR SYSTEM	133	
<i>Adefin XL 30 (AF)</i>		
.CARDIOVASCULAR SYSTEM	133	
<i>Adefin XL 60 (AF)</i>		
.CARDIOVASCULAR SYSTEM	133	
ADEFOVIR DIPIVOXIL		
.Section 100	744, 1001	
<i>Adesan (AF)</i>		
.CARDIOVASCULAR SYSTEM	143, 144	
<i>Adesan HCT 16/12.5 (AF)</i>		
.CARDIOVASCULAR SYSTEM	147	
<i>Adesan HCT 32/12.5 (AF)</i>		
.CARDIOVASCULAR SYSTEM	147	
<i>Adesan HCT 32/25 (AF)</i>		
.CARDIOVASCULAR SYSTEM	148	
ADRENALINE		
.CARDIOVASCULAR SYSTEM	122	
.RESPIRATORY SYSTEM	602	
<i>ADT Booster (CS)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE	255	
.Prescriber Bag	56	
<i>Advantan (BN)</i>		
.DERMATOLOGICALS	196	
<i>Aeron 250 (QA)</i>		
.RESPIRATORY SYSTEM	601	
<i>Aeron 500 (QA)</i>		
.RESPIRATORY SYSTEM	601	
<i>Afinitor (NV)</i>		
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	267, 268, 269	
AFLIBERCEPT		
.SENSORY ORGANS	614	
<i>Aggrastat (AS)</i>		
.BLOOD AND BLOOD FORMING ORGANS	110	
<i>Airomir Autohaler (IA)</i>		
.RESPIRATORY SYSTEM	595	

GENERIC/PROPRIETARY INDEX

<i>Akamin 50 (AF)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	224	
<i>Akineton (LM)</i>		
.NERVOUS SYSTEM.....	538	
<i>Albalon Liquifilm (AG)</i>		
.Repatriation Schedule.....	1269	
<i>Albalon-A (AG)</i>		
.Repatriation Schedule.....	1269	
ALBENDAZOLE		
.ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS.....	592	
<i>Albey Bee Venom (HL)</i>		
.VARIOUS.....	626	
<i>Albey Paper Wasp Venom (HL)</i>		
.VARIOUS.....	626	
<i>Albey Yellow Jacket Venom (HL)</i>		
.VARIOUS.....	626	
<i>Aldactone (PF)</i>		
.CARDIOVASCULAR SYSTEM.....	127	
<i>Aldara (IA)</i>		
.DERMATOLOGICALS.....	199	
.Repatriation Schedule.....	1254	
<i>Aldara Pump (IA)</i>		
.DERMATOLOGICALS.....	199	
.Repatriation Schedule.....	1254	
<i>Aldiq (QA)</i>		
.DERMATOLOGICALS.....	199	
.Repatriation Schedule.....	1254	
<i>Aldomet (AS)</i>		
.CARDIOVASCULAR SYSTEM.....	125	
ALEMTUZUMAB		
.Section 100.....	758, 759, 1015, 1016	
<i>Alendro Once Weekly (QA)</i>		
.MUSCULO-SKELETAL SYSTEM.....	498	
<i>Alendrobell 70mg (GQ)</i>		
.MUSCULO-SKELETAL SYSTEM.....	498	
ALENDRONATE		
.MUSCULO-SKELETAL SYSTEM.....	497	
ALENDRONATE + COLECALCIFEROL		
.MUSCULO-SKELETAL SYSTEM.....	502, 503	
.Repatriation Schedule.....	1261	
ALENDRONATE + COLECALCIFEROL (&) CALCIUM CARBONATE		
.MUSCULO-SKELETAL SYSTEM.....	503	
.Repatriation Schedule.....	1261	
<i>Alendronate AN (EA)</i>		
.MUSCULO-SKELETAL SYSTEM.....	498	
<i>Alendronate D3 70 mg/140 microgram (UA)</i>		
.MUSCULO-SKELETAL SYSTEM.....	502	
<i>Alendronate D3 70 mg/70 microgram (UA)</i>		
.MUSCULO-SKELETAL SYSTEM.....	503	
<i>Alendronate Plus D3 and Calcium Sandoz (SZ)</i>		
.MUSCULO-SKELETAL SYSTEM.....	504	
<i>Alendronate Plus D3 Calcium Actavis (UA)</i>		
.MUSCULO-SKELETAL SYSTEM.....	504	
<i>Alendronate plus D3-DRLA (RZ)</i>		
.MUSCULO-SKELETAL SYSTEM.....	502, 503	
.Repatriation Schedule.....	1261	
<i>Alendronate Sandoz (SZ)</i>		
.MUSCULO-SKELETAL SYSTEM.....	498	
<i>Alendronate-GA (GN)</i>		
.MUSCULO-SKELETAL SYSTEM.....	498	
<i>Alepam 15 (AF)</i>		
.NERVOUS SYSTEM.....	561	
.Palliative Care.....	675	
<i>Alepam 30 (AF)</i>		
.NERVOUS SYSTEM.....	561	
.Palliative Care.....	675	
<i>Alfamino (NT)</i>		
.VARIOUS.....	641, 643	
<i>Alfaré (NT)</i>		
.VARIOUS.....	646	
ALFUZOSIN		
.Repatriation Schedule.....	1257	
ALGINATE SODIUM + CALCIUM CARBONATE + BICARBONATE		
.ALIMENTARY TRACT AND METABOLISM.....	67	
<i>Algisite M 66000519 (SN)</i>		
.Repatriation Schedule.....	1277	
<i>Algisite M 66000520 (SN)</i>		
.Repatriation Schedule.....	1277	
<i>Algisite M 66000521 (SN)</i>		
.Repatriation Schedule.....	1277	
<i>Alkeran (AS)</i>		
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS.....	256	
<i>Allegron (AS)</i>		
.NERVOUS SYSTEM.....	564	
<i>Allereze (AF)</i>		
.Repatriation Schedule.....	1268	
<i>Allelyn 66007637 (SN)</i>		
.Repatriation Schedule.....	1278	
<i>Allelyn Adhesive 66000044 (SN)</i>		
.Repatriation Schedule.....	1278	
<i>Allelyn Ag Adhesive 66800073 (SN)</i>		
.Repatriation Schedule.....	1280	
<i>Allelyn Ag Adhesive 66800075 (SN)</i>		
.Repatriation Schedule.....	1280	
<i>Allelyn Ag Adhesive 66800078 (SN)</i>		
.Repatriation Schedule.....	1280	
<i>Allelyn Ag Gentle Border 66800460 (SN)</i>		
.Repatriation Schedule.....	1280	
<i>Allelyn Ag Gentle Border 66800461 (SN)</i>		
.Repatriation Schedule.....	1280	
<i>Allelyn Ag Gentle Border 66800462 (SN)</i>		
.Repatriation Schedule.....	1280	
<i>Allelyn Ag Non-Adhesive 66800086 (SN)</i>		
.Repatriation Schedule.....	1280	
<i>Allelyn Gentle 66800248 (SN)</i>		
.Repatriation Schedule.....	1279	

GENERIC/PROPRIETARY INDEX

<i>Allevyn Gentle Border 66800269 (SN)</i>	
.Repatriation Schedule	1279
<i>Allevyn Gentle Border 66800270 (SN)</i>	
.Repatriation Schedule	1279
<i>Allevyn Life 66801067 (SN)</i>	
.Repatriation Schedule	1278
<i>Allevyn Life 66801068 (SN)</i>	
.Repatriation Schedule	1278
<i>Allevyn Life 66801069 (SN)</i>	
.Repatriation Schedule	1279
<i>Allevyn Life 66801070 (SN)</i>	
.Repatriation Schedule	1279
<i>Allevyn Plus Cavity 66047571 (SN)</i>	
.Repatriation Schedule	1280
<i>Allevyn Plus Cavity 66047573 (SN)</i>	
.Repatriation Schedule	1280
<i>Allevyn Thin 66047576 (SN)</i>	
.Repatriation Schedule	1281
<i>Allevyn Thin 66047578 (SN)</i>	
.Repatriation Schedule	1281
<i>Allmercap (LM)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	258
ALLOPURINOL	
.MUSCULO-SKELETAL SYSTEM	497
<i>Allopurinol Sandoz (SZ)</i>	
.MUSCULO-SKELETAL SYSTEM	497
<i>Allosig (FM)</i>	
.MUSCULO-SKELETAL SYSTEM	497
<i>Alodorm (AF)</i>	
.NERVOUS SYSTEM	529, 561, 562
.Palliative Care	675
ALOGLIPTIN	
.ALIMENTARY TRACT AND METABOLISM	93
ALOGLIPTIN + METFORMIN	
.ALIMENTARY TRACT AND METABOLISM	85
<i>Aloxi (TS)</i>	
.ALIMENTARY TRACT AND METABOLISM	71
<i>Alpha Keri Bath Oil (MT)</i>	
.Repatriation Schedule	1251
<i>Alpha Keri Lotion (MT)</i>	
.Repatriation Schedule	1251
<i>Alphagan (AG)</i>	
.SENSORY ORGANS	608
<i>Alphagan P 1.5 (AG)</i>	
.SENSORY ORGANS	608
<i>Alphamox 125 (AF)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE	225
<i>Alphamox 250 (AF)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE	225, 226
<i>Alphamox 500 (AF)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE	226
<i>Alphapress 25 (AF)</i>	
.CARDIOVASCULAR SYSTEM	125
<i>Alphapress 50 (AF)</i>	
.CARDIOVASCULAR SYSTEM	125
<i>Alprax 0.25 (QA)</i>	
.NERVOUS SYSTEM	560
<i>Alprax 0.5 (QA)</i>	
.NERVOUS SYSTEM	560
<i>Alprax 1 (QA)</i>	
.NERVOUS SYSTEM	560
<i>Alprax 2 (QA)</i>	
.NERVOUS SYSTEM	560
ALPRAZOLAM	
.NERVOUS SYSTEM	560
<i>Alprim (AF)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE	237
ALPROSTADIL	
.Repatriation Schedule	1256
<i>Altven (FZ)</i>	
.NERVOUS SYSTEM	572, 573
ALUMINIUM HYDROXIDE + MAGNESIUM HYDROXIDE + MAGNESIUM TRISILICATE	
.ALIMENTARY TRACT AND METABOLISM	60
ALUMINIUM HYDROXIDE WITH MAGNESIUM HYDROXIDE	
.ALIMENTARY TRACT AND METABOLISM	60
ALUMINIUM HYDROXIDE WITH MAGNESIUM HYDROXIDE AND SIMETHICONE	
.Repatriation Schedule	1244
<i>Alvesco 160 (NQ)</i>	
.RESPIRATORY SYSTEM	601
<i>Alvesco 80 (NQ)</i>	
.RESPIRATORY SYSTEM	601
<i>Alzene (AF)</i>	
.Repatriation Schedule	1268
AMANTADINE	
.NERVOUS SYSTEM	540
<i>Amaryl (SW)</i>	
.ALIMENTARY TRACT AND METABOLISM	85
AMBRISENTAN	
.Section 100	687, 942
AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT METHIONINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID	
.VARIOUS	650
AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE AND TYROSINE, AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID	
.VARIOUS	651
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN	
.VARIOUS	651, 652
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE	
.VARIOUS	652

GENERIC/PROPRIETARY INDEX

AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, THREONINE AND VALINE AND LOW IN ISOLEUCINE .VARIOUS.....	652
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE .VARIOUS.....	653
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE .VARIOUS.....	654
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE .VARIOUS.....	654
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE WITH FAT, CARBOHYDRATE AND TRACE ELEMENTS AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID .VARIOUS.....	655
AMINO ACID FORMULA WITH VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS WITHOUT PHENYLALANINE .VARIOUS.....	651
AMINO ACID FORMULA WITHOUT PHENYLALANINE .VARIOUS.....	651
AMINO ACID FORMULA WITHOUT VALINE, LEUCINE AND ISOLEUCINE .VARIOUS.....	651
AMINO ACID SYNTHETIC FORMULA .VARIOUS.....	633, 634, 636
AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS .VARIOUS.....	636, 638
AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES .VARIOUS.....	639, 640, 642, 643
AMIODARONE .CARDIOVASCULAR SYSTEM	122
<i>Amiodarone Actavis (GN)</i> .CARDIOVASCULAR SYSTEM	122
<i>Amiodarone Sandoz (SZ)</i> .CARDIOVASCULAR SYSTEM	122
<i>Amipride 400 (QA)</i> .NERVOUS SYSTEM.....	554
<i>Amira 150 (AF)</i> .NERVOUS SYSTEM.....	569
<i>Amira 300 (AF)</i> .NERVOUS SYSTEM.....	569
AMISULPRIDE .NERVOUS SYSTEM.....	554
<i>Amisulpride 100 Winthrop (WA)</i> .NERVOUS SYSTEM.....	554
<i>Amisulpride 200 Winthrop (WA)</i> .NERVOUS SYSTEM.....	554
<i>Amisulpride 400 Winthrop (WA)</i> .NERVOUS SYSTEM.....	554
<i>Amisulpride Sandoz (SZ)</i> .NERVOUS SYSTEM.....	554
AMITRIPTYLINE .NERVOUS SYSTEM.....	563
<i>Amla 10 (QA)</i> .CARDIOVASCULAR SYSTEM	132
<i>Amla 5 (QA)</i> .CARDIOVASCULAR SYSTEM	132
AMLODIPINE .CARDIOVASCULAR SYSTEM	132
AMLODIPINE + ATORVASTATIN .CARDIOVASCULAR SYSTEM	189
AMLODIPINE + VALSARTAN .CARDIOVASCULAR SYSTEM	152
AMLODIPINE + VALSARTAN + HYDROCHLOROTHIAZIDE .CARDIOVASCULAR SYSTEM	153
<i>Amlodipine AN (EA)</i> .CARDIOVASCULAR SYSTEM	132
<i>Amlodipine generichealth (GQ)</i> .CARDIOVASCULAR SYSTEM	132
<i>Amlodipine Sandoz (SZ)</i> .CARDIOVASCULAR SYSTEM	132
<i>Amlodipine-DRLA (RZ)</i> .CARDIOVASCULAR SYSTEM	132
AMMONIUM + SENEGA ROOT .Repatriation Schedule	1267
AMOROLFINE .Repatriation Schedule	1250
<i>Amoxil (AS)</i> .ANTIINFECTIVES FOR SYSTEMIC USE	225, 226
<i>Amoxil Forte (AS)</i> .ANTIINFECTIVES FOR SYSTEMIC USE	226
AMOXYCILLIN .ANTIINFECTIVES FOR SYSTEMIC USE	225, 226
AMOXYCILLIN + CLAVULANIC ACID .ANTIINFECTIVES FOR SYSTEMIC USE	229
<i>Amoxycillin AN (EA)</i> .ANTIINFECTIVES FOR SYSTEMIC USE	225, 226
<i>Amoxycillin generichealth 500 (GQ)</i> .ANTIINFECTIVES FOR SYSTEMIC USE	226
<i>Amoxycillin Ranbaxy (RA)</i> .ANTIINFECTIVES FOR SYSTEMIC USE	225, 226
<i>Amoxycillin Sandoz (BG)</i> .ANTIINFECTIVES FOR SYSTEMIC USE	225
<i>Amoxycillin Sandoz (SZ)</i> .ANTIINFECTIVES FOR SYSTEMIC USE	225, 226
<i>Amoxycillin-GA (GN)</i> .ANTIINFECTIVES FOR SYSTEMIC USE	225, 226
<i>Amoxyclav AN 500/125 (EA)</i> .ANTIINFECTIVES FOR SYSTEMIC USE	229
<i>Amoxyclav AN 875/125 (EA)</i> .ANTIINFECTIVES FOR SYSTEMIC USE	230
<i>AmoxyClav GH 875/125 (GQ)</i> .ANTIINFECTIVES FOR SYSTEMIC USE	230

GENERIC/PROPRIETARY INDEX

<i>AmoxyClav RBX 875/125 (RA)</i>		<i>Andriol Testocaps (MK)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	230	.GENITO URINARY SYSTEM AND SEX HORMONES .	206
AMPHOTERICIN B		<i>Androcur (BN)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	60	.ANTINEOPLASTIC AND IMMUNOMODULATING	
AMPICILLIN		AGENTS	295
.ANTIINFECTIVES FOR SYSTEMIC USE.....	226	.GENITO URINARY SYSTEM AND SEX HORMONES .	211
<i>Ampicyn (AF)</i>		<i>Androcur-100 (BN)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	226, 227	.ANTINEOPLASTIC AND IMMUNOMODULATING	
AMYLOPECTIN MODIFIED LONG CHAIN		AGENTS	295
.VARIOUS.....	649	.GENITO URINARY SYSTEM AND SEX HORMONES .	211
<i>Anafranil 25 (NV)</i>		<i>Androderm (GN)</i>	
.NERVOUS SYSTEM.....	563	.GENITO URINARY SYSTEM AND SEX HORMONES .	204
<i>Anamorph (FM)</i>		<i>Anginine Stabilised (QA)</i>	
.NERVOUS SYSTEM.....	513, 514	.CARDIOVASCULAR SYSTEM	123
<i>Anandron (SW)</i>		<i>Angiomax (XM)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING		.BLOOD AND BLOOD FORMING ORGANS.....	110
AGENTS	296	<i>Anoro Ellipta 62.5/25 (GK)</i>	
<i>Anapen (LM)</i>		.RESPIRATORY SYSTEM.....	600
.CARDIOVASCULAR SYSTEM	123	<i>Anpec 40 (AF)</i>	
.RESPIRATORY SYSTEM	602	.CARDIOVASCULAR SYSTEM	134
<i>Anapen Junior (LM)</i>		<i>Anpec 80 (AF)</i>	
.CARDIOVASCULAR SYSTEM	123	.CARDIOVASCULAR SYSTEM	134
.RESPIRATORY SYSTEM	602	<i>Antenex 2 (AF)</i>	
<i>Anaprox 550 (RO)</i>		.NERVOUS SYSTEM.....	560, 561
.MUSCULO-SKELETAL SYSTEM	494	.Palliative Care.....	674, 675
.Palliative Care	670	<i>Antenex 5 (AF)</i>	
<i>Anastrol (QA)</i>		.NERVOUS SYSTEM.....	560, 561
.ANTINEOPLASTIC AND IMMUNOMODULATING		.Palliative Care.....	674, 675
AGENTS	296	<i>Anthel 125 (AF)</i>	
ANASTROZOLE		.ANTIPARASITIC PRODUCTS, INSECTICIDES AND	
.ANTINEOPLASTIC AND IMMUNOMODULATING		REPELLENTS.....	592
AGENTS	296	<i>Anthel 250 (AF)</i>	
<i>Anastrozole AN (EA)</i>		.ANTIPARASITIC PRODUCTS, INSECTICIDES AND	
.ANTINEOPLASTIC AND IMMUNOMODULATING		REPELLENTS.....	592
AGENTS	297	<i>Antroquoril (FR)</i>	
<i>Anastrozole FBM (FO)</i>		.DERMATOLOGICALS.....	196
.ANTINEOPLASTIC AND IMMUNOMODULATING		<i>Anusol (JT)</i>	
AGENTS	297	.Repatriation Schedule	1249
<i>Anastrozole GH (GQ)</i>		<i>Anzole (UA)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING		.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	297	AGENTS	297
<i>Anastrozole RBX (RA)</i>		<i>Apidra (AV)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING		.ALIMENTARY TRACT AND METABOLISM.....	81
AGENTS	297	<i>Apidra (SW)</i>	
<i>Anastrozole Sandoz (SZ)</i>		.ALIMENTARY TRACT AND METABOLISM.....	81
.ANTINEOPLASTIC AND IMMUNOMODULATING		<i>Apidra SoloStar (SW)</i>	
AGENTS	297	.ALIMENTARY TRACT AND METABOLISM.....	81
<i>Anastrozole-DRLA (RZ)</i>		APIXABAN	
.ANTINEOPLASTIC AND IMMUNOMODULATING		.BLOOD AND BLOOD FORMING ORGANS.....	112, 113
AGENTS	297	<i>APO- Hydroxychloroquine (TX)</i>	
<i>Anastrozole-GA (GN)</i>		.MUSCULO-SKELETAL SYSTEM	495
.ANTINEOPLASTIC AND IMMUNOMODULATING		<i>APO- Paracetamol/Codeine 500/30 (TX)</i>	
AGENTS	297	.NERVOUS SYSTEM.....	516, 517
<i>Andepra (EL)</i>		<i>APO-Adefovir (TX)</i>	
.NERVOUS SYSTEM.....	570	.Section 100.....	745, 1001

GENERIC/PROPRIETARY INDEX

<i>APO-Alendronate (TX)</i>	
.MUSCULO-SKELETAL SYSTEM	498
<i>APO-Alendronate Plus D3 70 mg/140 mcg (TX)</i>	
.MUSCULO-SKELETAL SYSTEM	502
<i>APO-Alendronate Plus D3 70 mg/70 mcg (TX)</i>	
.MUSCULO-SKELETAL SYSTEM	503
<i>APO-Allopurinol (TX)</i>	
.MUSCULO-SKELETAL SYSTEM	497
<i>APO-Amisulpride (TX)</i>	
.NERVOUS SYSTEM.....	554
<i>APO-Amitriptyline 10 (TX)</i>	
.NERVOUS SYSTEM.....	563
<i>APO-Amitriptyline 25 (TX)</i>	
.NERVOUS SYSTEM.....	563
<i>APO-Amitriptyline 50 (TX)</i>	
.NERVOUS SYSTEM.....	563
<i>APO-Amlodipine (TX)</i>	
.CARDIOVASCULAR SYSTEM	132
<i>APO-Amlodipine/Atorvastatin 10/10 (TX)</i>	
.CARDIOVASCULAR SYSTEM	189
<i>APO-Amlodipine/Atorvastatin 10/20 (TX)</i>	
.CARDIOVASCULAR SYSTEM	190
<i>APO-Amlodipine/Atorvastatin 10/40 (TX)</i>	
.CARDIOVASCULAR SYSTEM	190
<i>APO-Amlodipine/Atorvastatin 10/80 (TX)</i>	
.CARDIOVASCULAR SYSTEM	190
<i>APO-Amlodipine/Atorvastatin 5/10 (TX)</i>	
.CARDIOVASCULAR SYSTEM	190
<i>APO-Amlodipine/Atorvastatin 5/20 (TX)</i>	
.CARDIOVASCULAR SYSTEM	190
<i>APO-Amlodipine/Atorvastatin 5/40 (TX)</i>	
.CARDIOVASCULAR SYSTEM	191
<i>APO-Amlodipine/Atorvastatin 5/80 (TX)</i>	
.CARDIOVASCULAR SYSTEM	191
<i>APO-Amoxycillin (TX)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	225, 226
<i>APO-Amoxycillin and Clavulanic Acid (TX)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	230
<i>APO-Amoxycillin and Clavulanic Acid 125/31.25 (TX)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	229
<i>APO-Amoxycillin and Clavulanic Acid 400/57 (TX)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	229
<i>APO-Amoxycillin/ Clavulanic Acid 500/125 (TX)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	229
<i>APO-Anastrozole (TX)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	297
<i>APO-Atenolol (TX)</i>	
.CARDIOVASCULAR SYSTEM	128
<i>APO-Atorvastatin (TX)</i>	
.CARDIOVASCULAR SYSTEM	156, 157, 158
<i>APO-Azathioprine (TX)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	489
<i>APO-Azithromycin (TX)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	238
.Repatriation Schedule	1259
.SENSORY ORGANS.....	605
<i>APO-Bicalutamide (TX)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	295
<i>APO-Bisoprolol (TX)</i>	
.CARDIOVASCULAR SYSTEM	129
<i>APO-Candesartan (TX)</i>	
.CARDIOVASCULAR SYSTEM	143, 144
<i>APO-Candesartan HCTZ 16/12.5 (TX)</i>	
.CARDIOVASCULAR SYSTEM	147
<i>APO-Candesartan HCTZ 32/12.5 (TX)</i>	
.CARDIOVASCULAR SYSTEM	148
<i>APO-Candesartan HCTZ 32/25 (TX)</i>	
.CARDIOVASCULAR SYSTEM	148
<i>APO-Carvedilol (TX)</i>	
.CARDIOVASCULAR SYSTEM	131
<i>APO-Cefaclor (TX)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	234
<i>APO-Cefaclor CD (TX)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	234
<i>APO-Celecoxib (TX)</i>	
.MUSCULO-SKELETAL SYSTEM	495
<i>APO-Cephalexin (TX)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	231, 232
<i>APO-Citalopram (TX)</i>	
.NERVOUS SYSTEM.....	564
<i>APO-Clarithromycin (TX)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	238
<i>APO-Clindamycin (TX)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	240
<i>APO-Clopidogrel (TX)</i>	
.BLOOD AND BLOOD FORMING ORGANS.....	106, 107
.Repatriation Schedule	1248
<i>APO-Clopidogrel/Aspirin 75/100 (TX)</i>	
.BLOOD AND BLOOD FORMING ORGANS.....	108
<i>APO-Clotrimazole 3 Day Cream (TX)</i>	
.Repatriation Schedule	1256
<i>APO-Clotrimazole 6 Day Cream (TX)</i>	
.Repatriation Schedule	1256
<i>APO-Diazepam (TX)</i>	
.NERVOUS SYSTEM.....	560, 561
.Palliative Care.....	674, 675
<i>APO-Diclofenac (TX)</i>	
.MUSCULO-SKELETAL SYSTEM	490
.Palliative Care.....	667, 668
<i>APO-Dipyridamole/Aspirin 200/25 (TX)</i>	
.BLOOD AND BLOOD FORMING ORGANS.....	109
<i>APO-Donepezil (TX)</i>	
.NERVOUS SYSTEM.....	576, 578
<i>APO-Duloxetine (TX)</i>	
.NERVOUS SYSTEM.....	570
<i>APO-Enalapril (TX)</i>	
.CARDIOVASCULAR SYSTEM	135

GENERIC/PROPRIETARY INDEX

<i>APO-Escitalopram (TX)</i>	
.NERVOUS SYSTEM.....	565
<i>APO-Exemestane (TX)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	297, 298
<i>APO-Famciclovir (TX)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	251, 252, 253
<i>APO-Finasteride (TX)</i>	
.Repatriation Schedule	1258
<i>APO-Fluconazole (TX)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	246
<i>APO-Fluvoxamine (TX)</i>	
.NERVOUS SYSTEM.....	567
<i>APO-Fosinopril (TX)</i>	
.CARDIOVASCULAR SYSTEM	135, 136
<i>APO-Fosinopril HCTZ 10/12.5 (TX)</i>	
.CARDIOVASCULAR SYSTEM	141
<i>APO-Fosinopril HCTZ 20/12.5 (TX)</i>	
.CARDIOVASCULAR SYSTEM	141
<i>APO-Frusemide (TX)</i>	
.CARDIOVASCULAR SYSTEM	126, 127
<i>APO-Gabapentin (TX)</i>	
.NERVOUS SYSTEM.....	531
.Repatriation Schedule	1263
<i>APO-Galantamine MR (TX)</i>	
.NERVOUS SYSTEM.....	579, 580
<i>APO-Gliclazide MR (TX)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	84
<i>APO-Glimepiride (TX)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	84, 85
<i>APO-Imiquimod (TX)</i>	
.DERMATOLOGICALS.....	199
.Repatriation Schedule	1254
<i>APO-Indapamide SR (TX)</i>	
.CARDIOVASCULAR SYSTEM	126
<i>APO-Ipratropium (TX)</i>	
.RESPIRATORY SYSTEM	601
<i>APO-Irbesartan (TX)</i>	
.CARDIOVASCULAR SYSTEM	145
<i>APO-Irbesartan HCTZ (TX)</i>	
.CARDIOVASCULAR SYSTEM	149
<i>APO-Isotretinoin (TX)</i>	
.DERMATOLOGICALS.....	197
<i>APO-Lamotrigine (TX)</i>	
.NERVOUS SYSTEM.....	534
<i>APO-Lansoprazole (TX)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	63
<i>APO-Latanoprost (TX)</i>	
.SENSORY ORGANS.....	612
<i>APO-Latanoprost/Timolol 0.05/5 (TX)</i>	
.SENSORY ORGANS.....	613
<i>APO-Leflunomide (TX)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	315
<i>APO-Lercanidipine (TX)</i>	
.CARDIOVASCULAR SYSTEM	133
<i>APO-Letrozole (TX)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	298
<i>APO-Levetiracetam (TX)</i>	
.NERVOUS SYSTEM.....	535
<i>APO-Lisinopril (TX)</i>	
.CARDIOVASCULAR SYSTEM	136
<i>APO-MACROGOL plus ELECTROLYTES (TX)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	75
.Palliative Care.....	664, 665
<i>APO-Meloxicam (TX)</i>	
.MUSCULO-SKELETAL SYSTEM	491, 492
<i>APO-Memantine (TX)</i>	
.NERVOUS SYSTEM.....	583
<i>APO-Metformin 1000 (TX)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	83
<i>APO-Metformin 500 (TX)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	83
<i>APO-Metformin 850 (TX)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	84
<i>APO-Metformin XR 1000 (TX)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	83
<i>APO-Metformin XR 500 (TX)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	84
<i>APO-Metoclopramide (TX)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	67
<i>APO-Metoprolol (TX)</i>	
.CARDIOVASCULAR SYSTEM	130
<i>Apomine (HH)</i>	
.Section 100.....	920, 1178
<i>Apomine PFS (HH)</i>	
.Section 100.....	920, 1178
<i>APO-Mirtazapine (TX)</i>	
.NERVOUS SYSTEM.....	572
<i>APO-Montelukast (TX)</i>	
.RESPIRATORY SYSTEM.....	603, 604
<i>APOMORPHINE</i>	
.Section 100.....	920, 1178
<i>APO-Mycophenolate (TX)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	316
.Section 100.....	802, 803, 1061
<i>APO-Nifedipine XR (TX)</i>	
.CARDIOVASCULAR SYSTEM	133
<i>APO-Olanzapine (TX)</i>	
.NERVOUS SYSTEM.....	547, 549, 550, 551
<i>APO-Olanzapine ODT (TX)</i>	
.NERVOUS SYSTEM.....	546, 548, 549
<i>APO-Omeprazole (TX)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	63, 64
<i>APO-Ondansetron (TX)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	69, 70
<i>APO-Oxazepam (TX)</i>	
.NERVOUS SYSTEM.....	561

GENERIC/PROPRIETARY INDEX

.Palliative Care	675	.CARDIOVASCULAR SYSTEM	122
<i>APO-Pantoprazole (TX)</i>		<i>APO-Sumatriptan (TX)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	65	.NERVOUS SYSTEM.....	526
<i>APO-Paracetamol (TX)</i>		<i>APO-Telmisartan (TX)</i>	
.NERVOUS SYSTEM.....	523, 524	.CARDIOVASCULAR SYSTEM	146
<i>APO-Perindopril (TX)</i>		<i>APO-Telmisartan HCTZ 40/12.5 (TX)</i>	
.CARDIOVASCULAR SYSTEM	137	.CARDIOVASCULAR SYSTEM	150
<i>APO-Pramipexole (TX)</i>		<i>APO-Telmisartan HCTZ 80/12.5 (TX)</i>	
.NERVOUS SYSTEM.....	541	.CARDIOVASCULAR SYSTEM	150
<i>APO-Pravastatin (TX)</i>		<i>APO-Telmisartan HCTZ 80/25 (TX)</i>	
.CARDIOVASCULAR SYSTEM	159, 160, 161	.CARDIOVASCULAR SYSTEM	151
<i>APO-Prazosin (TX)</i>		<i>APO-Temazepam (TX)</i>	
.CARDIOVASCULAR SYSTEM	125	.NERVOUS SYSTEM.....	562
<i>APO-Prochlorperazine (TX)</i>		.Palliative Care.....	676
.ALIMENTARY TRACT AND METABOLISM.....	72	<i>APOTEX-MORPHINE MR (TX)</i>	
<i>APO-Quetiapine (TX)</i>		.NERVOUS SYSTEM.....	513
.NERVOUS SYSTEM.....	552, 553, 554	<i>APOTEX-Pioglitazone (TX)</i>	
<i>APO-Quinapril (TX)</i>		.ALIMENTARY TRACT AND METABOLISM.....	92
.CARDIOVASCULAR SYSTEM	138	<i>APO-Topiramate (TX)</i>	
<i>APO-Rabeprazole (TX)</i>		.NERVOUS SYSTEM.....	537, 538
.ALIMENTARY TRACT AND METABOLISM.....	66	<i>APO-Tramadol (TX)</i>	
<i>APO-Raloxifene (TX)</i>		.NERVOUS SYSTEM.....	522, 523
.MUSCULO-SKELETAL SYSTEM	508	<i>APO-Tramadol SR (TX)</i>	
<i>APO-Ramipril (TX)</i>		.NERVOUS SYSTEM.....	521
.CARDIOVASCULAR SYSTEM	138, 139, 140	<i>APO-Trandolapril (TX)</i>	
<i>APO-Ranitidine (TX)</i>		.CARDIOVASCULAR SYSTEM	140
.ALIMENTARY TRACT AND METABOLISM.....	61	<i>APO-Valaciclovir (TX)</i>	
<i>APO-Riluzole (TX)</i>		.ANTIINFECTIVES FOR SYSTEMIC USE.....	253, 254
.NERVOUS SYSTEM.....	590	.Section 100.....	737, 993
<i>APO-Risedronate (TX)</i>		<i>APO-Valsartan (TX)</i>	
.MUSCULO-SKELETAL SYSTEM	500	.CARDIOVASCULAR SYSTEM	147
.Repatriation Schedule.....	1261	<i>APO-Valsartan HCTZ 160/12.5 (TX)</i>	
<i>APO-Risperidone (TX)</i>		.CARDIOVASCULAR SYSTEM	151
.NERVOUS SYSTEM.....	556, 557, 558, 559	<i>APO-Valsartan HCTZ 320/12.5 (TX)</i>	
<i>APO-Rosuvastatin (TX)</i>		.CARDIOVASCULAR SYSTEM	151
.CARDIOVASCULAR SYSTEM... 161, 162, 163, 164, 165		<i>APO-Valsartan HCTZ 320/25 (TX)</i>	
<i>APO-Roxithromycin (TX)</i>		.CARDIOVASCULAR SYSTEM	151
.ANTIINFECTIVES FOR SYSTEMIC USE.....	239, 240	<i>APO-Venlafaxine XR (TX)</i>	
<i>Aporyl (TX)</i>		.NERVOUS SYSTEM.....	572, 573
.Repatriation Schedule.....	1250	<i>APO-Ziprasidone (TX)</i>	
<i>APO-Salbutamol (TX)</i>		.NERVOUS SYSTEM.....	545
.Prescriber Bag	57, 58	<i>APO-Zolmitriptan (TX)</i>	
.RESPIRATORY SYSTEM	594, 595	.NERVOUS SYSTEM.....	527
<i>APO-Salbutamol Inhaler (TX)</i>		APRACLOPIDINE	
.Prescriber Bag	57	.SENSORY ORGANS.....	608
.RESPIRATORY SYSTEM	594	APREPITANT	
<i>APO-Sertraline (TX)</i>		.ALIMENTARY TRACT AND METABOLISM.....	71
.NERVOUS SYSTEM.....	568	<i>Aptivus (BY)</i>	
<i>APO-Sildenafil (TX)</i>		.Section 100.....	744, 1000
.Repatriation Schedule.....	1256, 1257	<i>Aquacare H.P. (AG)</i>	
<i>APO-Sildenafil PHT (TX)</i>		.Repatriation Schedule.....	1251
.Section 100	727, 982	<i>Aquacel 403770 (CC)</i>	
<i>APO-Simvastatin (TX)</i>		.Repatriation Schedule.....	1283
.CARDIOVASCULAR SYSTEM	166, 167, 168	<i>Aquacel Ag 403708 (CC)</i>	
<i>APO-Sotalol (TX)</i>		.Repatriation Schedule.....	1284

GENERIC/PROPRIETARY INDEX

<i>Aquacel Ag 403710 (CC)</i>		<i>Aridon APN 10 (FM)</i>	
.Repatriation Schedule	1284	.NERVOUS SYSTEM	576, 578
<i>Aquacel Ag 403771 (CC)</i>		<i>Aridon APN 5 (FM)</i>	
.Repatriation Schedule	1284	.NERVOUS SYSTEM	577, 578
<i>Aquacel Extra 420672 (CC)</i>		<i>Arimidex (AP)</i>	
.Repatriation Schedule	1283	.ANTINEOPLASTIC AND IMMUNOMODULATING	
<i>Aquacel Extra 420673 (CC)</i>		AGENTS	297
.Repatriation Schedule	1283	ARIPRAZOLE	
<i>Aquasun Lotion SPF 18 (PF)</i>		.NERVOUS SYSTEM	555
.Repatriation Schedule	1251	<i>Aristocort 0.02% (QA)</i>	
<i>Aquinafil (GN)</i>		.DERMATOLOGICALS	195
.CARDIOVASCULAR SYSTEM	138	<i>Arixtra (AS)</i>	
<i>Arablox (AV)</i>		.BLOOD AND BLOOD FORMING ORGANS	118
.ANTINEOPLASTIC AND IMMUNOMODULATING		<i>Aromasin (PF)</i>	
AGENTS	315, 316	.ANTINEOPLASTIC AND IMMUNOMODULATING	
ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID		AGENTS	297, 298
WITH CARBOHYDRATE		<i>Aropax (AS)</i>	
.VARIOUS	655	.NERVOUS SYSTEM	568
<i>Aranesp (AN)</i>		<i>Artane (QA)</i>	
.Section 100	684, 939	.NERVOUS SYSTEM	538
<i>Aranesp SureClick (AN)</i>		ARTEMETHER + LUMEFANTRINE	
.Section 100	684, 939	.ANTIPARASITIC PRODUCTS, INSECTICIDES AND	
<i>Aratac 100 (AF)</i>		REPELLENTS	591
.CARDIOVASCULAR SYSTEM	122	<i>Arthrexin (AF)</i>	
<i>Aratac 200 (AF)</i>		.MUSCULO-SKELETAL SYSTEM	491
.CARDIOVASCULAR SYSTEM	122	.Palliative Care	668
<i>Arava (SW)</i>		<i>Arthrotec 50 (PF)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING		.Repatriation Schedule	1261
AGENTS	315, 316	<i>Asasantin SR (BY)</i>	
<i>Arazil (AF)</i>		.BLOOD AND BLOOD FORMING ORGANS	109
.NERVOUS SYSTEM	576, 578	ASENAPINE	
<i>ARDIX GLICLAZIDE 60mg MR (RX)</i>		.NERVOUS SYSTEM	545
.ALIMENTARY TRACT AND METABOLISM	84	<i>Asmol 2.5 uni-dose (AF)</i>	
<i>Aredia 30 mg (NV)</i>		.Prescriber Bag	57
.MUSCULO-SKELETAL SYSTEM	499	.RESPIRATORY SYSTEM	594
.Section 100	918, 1176	<i>Asmol 5 uni-dose (AF)</i>	
<i>Aredia 90 mg (NV)</i>		.Prescriber Bag	57
.Section 100	919, 1177	.RESPIRATORY SYSTEM	595
<i>Arginine 2000 (VF)</i>		<i>Asmol CFC-free (AL)</i>	
.VARIOUS	655	.Prescriber Bag	57
<i>Arginine 500 (VF)</i>		.RESPIRATORY SYSTEM	594
.VARIOUS	655	<i>Aspalgin 40 (QA)</i>	
<i>Arginine 5000 (VF)</i>		.Repatriation Schedule	1263
.VARIOUS	655	<i>Aspen Methadone Syrup (QA)</i>	
ARGININE WITH CARBOHYDRATE		.Palliative Care	673
.VARIOUS	655	.Section 100	1208
<i>Arianna (AF)</i>		<i>Aspen Pharma Pty Ltd (QA)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING		.NERVOUS SYSTEM	527, 574
AGENTS	297	ASPIRIN	
<i>Aricept (PF)</i>		.BLOOD AND BLOOD FORMING ORGANS	106
.NERVOUS SYSTEM	576, 577, 578	.NERVOUS SYSTEM	523
<i>Aridon 10 (QA)</i>		.Repatriation Schedule	1248
.NERVOUS SYSTEM	576, 578	ASPIRIN + CODEINE	
<i>Aridon 5 (QA)</i>		.Repatriation Schedule	1263
.NERVOUS SYSTEM	577, 578	<i>Astrix (YN)</i>	

GENERIC/PROPRIETARY INDEX

.BLOOD AND BLOOD FORMING ORGANS	106
.Repatriation Schedule	1248
<i>Astromide (GN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	256, 257
<i>Atacand (AP)</i>	
.CARDIOVASCULAR SYSTEM	144
<i>Atacand Plus 16/12.5 (AP)</i>	
.CARDIOVASCULAR SYSTEM	147
<i>Atacand Plus 32/12.5 (AP)</i>	
.CARDIOVASCULAR SYSTEM	148
<i>Atacand Plus 32/25 (AP)</i>	
.CARDIOVASCULAR SYSTEM	148
ATAZANAVIR	
.Section 100	738, 994
ATENOLOL	
.CARDIOVASCULAR SYSTEM	128, 129
<i>Atenolol AN (EA)</i>	
.CARDIOVASCULAR SYSTEM	128
<i>Atenolol GH (GQ)</i>	
.CARDIOVASCULAR SYSTEM	128
<i>Atenolol Sandoz (SZ)</i>	
.CARDIOVASCULAR SYSTEM	128
<i>Atenolol-AFT (AE)</i>	
.CARDIOVASCULAR SYSTEM	129
<i>Atenolol-GA (GN)</i>	
.CARDIOVASCULAR SYSTEM	128
ATOMOXETINE	
.NERVOUS SYSTEM	573
<i>Atorvachol (GN)</i>	
.CARDIOVASCULAR SYSTEM	156, 157, 158
ATORVASTATIN	
.CARDIOVASCULAR SYSTEM	156, 157
ATORVASTATIN (&) EZETIMIBE	
.CARDIOVASCULAR SYSTEM	172, 175
<i>Atorvastatin AN (EA)</i>	
.CARDIOVASCULAR SYSTEM	156, 157, 158
<i>Atorvastatin GH (GQ)</i>	
.CARDIOVASCULAR SYSTEM	156, 157, 158
<i>Atorvastatin Pfizer (FZ)</i>	
.CARDIOVASCULAR SYSTEM	156, 157, 158
<i>Atorvastatin Sandoz (SZ)</i>	
.CARDIOVASCULAR SYSTEM	156, 157, 158
<i>Atorvastatin SCP 10 (RZ)</i>	
.CARDIOVASCULAR SYSTEM	156, 158
<i>Atorvastatin SCP 20 (RZ)</i>	
.CARDIOVASCULAR SYSTEM	157, 158
<i>Atorvastatin SCP 40 (RZ)</i>	
.CARDIOVASCULAR SYSTEM	157, 158
<i>Atorvastatin SCP 80 (RZ)</i>	
.CARDIOVASCULAR SYSTEM	157, 158
<i>Atorvastatin SZ (HX)</i>	
.CARDIOVASCULAR SYSTEM	156, 157, 158
ATOVAQUONE	
.ANTIPARASITIC PRODUCTS, INSECTICIDES AND	
REPELLENTS	591
ATOVAQUONE + PROGUANIL	
.ANTIPARASITIC PRODUCTS, INSECTICIDES AND	
REPELLENTS	591
<i>Atozet Composite Pack (MK)</i>	
.CARDIOVASCULAR SYSTEM	175, 178
<i>Atrauman 499513 (HR)</i>	
.Repatriation Schedule	1285
<i>Atrauman Ag 499572 (HR)</i>	
.Repatriation Schedule	1286
<i>Atripla (GI)</i>	
.Section 100	754, 1011
ATROPINE	
.ALIMENTARY TRACT AND METABOLISM	67
.SENSORY ORGANS	614
<i>Atropt (QA)</i>	
.SENSORY ORGANS	614
<i>Atrovent (BY)</i>	
.RESPIRATORY SYSTEM	601
<i>Atrovent Adult (BY)</i>	
.RESPIRATORY SYSTEM	602
<i>Atrovent Nasal Aqueous (BY)</i>	
.Repatriation Schedule	1267
<i>Atrovent Nasal Forte (BY)</i>	
.Repatriation Schedule	1267
<i>Aubagio (GZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	317
<i>Augmentin (AS)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE	229
<i>Augmentin Duo (AS)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE	229, 230
<i>Augmentin Duo 400 (AS)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE	229
<i>Augmentin Duo forte (AS)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE	230
AURANOFIN	
.MUSCULO-SKELETAL SYSTEM	495
<i>Auro-Amlodipine 10 (DO)</i>	
.CARDIOVASCULAR SYSTEM	132
<i>Auro-Amlodipine 5 (DO)</i>	
.CARDIOVASCULAR SYSTEM	132
<i>Auro-Candesartan 16 (DO)</i>	
.CARDIOVASCULAR SYSTEM	143
<i>Auro-Candesartan 32 (DO)</i>	
.CARDIOVASCULAR SYSTEM	144
<i>Auro-Candesartan 4 (DO)</i>	
.CARDIOVASCULAR SYSTEM	144
<i>Auro-Candesartan 8 (DO)</i>	
.CARDIOVASCULAR SYSTEM	144
<i>Auro-Citalopram 20 (DO)</i>	
.NERVOUS SYSTEM	564
<i>Auro-Citalopram 40 (DO)</i>	
.NERVOUS SYSTEM	565

GENERIC/PROPRIETARY INDEX

<i>Auro-Famciclovir 250 (DO)</i>		.ALIMENTARY TRACT AND METABOLISM..... 61
.ANTIINFECTIVES FOR SYSTEMIC USE.....	252	
<i>Auro-Famciclovir 500 (DO)</i>		<i>Austrapen (AL)</i>
.ANTIINFECTIVES FOR SYSTEMIC USE.....	253	.ANTIINFECTIVES FOR SYSTEMIC USE..... 226, 227
<i>Auro-Lisinopril 10 (DO)</i>		<i>Avandamet (GK)</i>
.CARDIOVASCULAR SYSTEM.....	136	.ALIMENTARY TRACT AND METABOLISM..... 87
<i>Auro-Lisinopril 20 (DO)</i>		<i>Avandia (GK)</i>
.CARDIOVASCULAR SYSTEM.....	136	.ALIMENTARY TRACT AND METABOLISM..... 93
<i>Auro-Lisinopril 5 (DO)</i>		<i>Avanza (MK)</i>
.CARDIOVASCULAR SYSTEM.....	136	.NERVOUS SYSTEM..... 572
<i>Auro-Montelukast Tabs 4 (DO)</i>		<i>Avanza SolTab (MK)</i>
.RESPIRATORY SYSTEM.....	603	.NERVOUS SYSTEM..... 571, 572
<i>Auro-Montelukast Tabs 5 (DO)</i>		<i>Avapro (AV)</i>
.RESPIRATORY SYSTEM.....	604	.CARDIOVASCULAR SYSTEM..... 145
<i>Auro-Pravastatin 10 (DO)</i>		<i>Avapro HCT 150/12.5 (AV)</i>
.CARDIOVASCULAR SYSTEM.....	159, 160	.CARDIOVASCULAR SYSTEM..... 149
<i>Auro-Pravastatin 20 (DO)</i>		<i>Avapro HCT 300/12.5 (AV)</i>
.CARDIOVASCULAR SYSTEM.....	159, 160	.CARDIOVASCULAR SYSTEM..... 149
<i>Auro-Pravastatin 40 (DO)</i>		<i>Avapro HCT 300/25 (AV)</i>
.CARDIOVASCULAR SYSTEM.....	160, 161	.CARDIOVASCULAR SYSTEM..... 149
<i>Auro-Pravastatin 80 (DO)</i>		<i>Avodart (GK)</i>
.CARDIOVASCULAR SYSTEM.....	160, 161	.GENITO URINARY SYSTEM AND SEX HORMONES . 213
<i>Aurorix (HM)</i>		.Repatriation Schedule..... 1258
.NERVOUS SYSTEM.....	569	<i>Avonex (BD)</i>
<i>Aurorix 300 mg (HM)</i>		.ANTINEOPLASTIC AND IMMUNOMODULATING
.NERVOUS SYSTEM.....	570	AGENTS 301
<i>Auro-Sertraline 100 (DO)</i>		<i>Axiron (LY)</i>
.NERVOUS SYSTEM.....	568, 569	.GENITO URINARY SYSTEM AND SEX HORMONES . 204
<i>Auro-Sertraline 50 (DO)</i>		<i>Axit 15 (AF)</i>
.NERVOUS SYSTEM.....	568, 569	.NERVOUS SYSTEM..... 572
<i>Auro-Simvastatin 10 (DO)</i>		<i>Axit 30 (AF)</i>
.CARDIOVASCULAR SYSTEM.....	166, 167	.NERVOUS SYSTEM..... 572
<i>Auro-Simvastatin 20 (DO)</i>		<i>Axit 45 (AF)</i>
.CARDIOVASCULAR SYSTEM.....	166, 167	.NERVOUS SYSTEM..... 572
<i>Auro-Simvastatin 40 (DO)</i>		<i>Aylide 1 (AF)</i>
.CARDIOVASCULAR SYSTEM.....	166, 168	.ALIMENTARY TRACT AND METABOLISM..... 84
<i>Auro-Simvastatin 80 (DO)</i>		<i>Aylide 2 (AF)</i>
.CARDIOVASCULAR SYSTEM.....	167, 168	.ALIMENTARY TRACT AND METABOLISM..... 85
AUROTHIOMALATE SODIUM		<i>Aylide 3 (AF)</i>
.MUSCULO-SKELETAL SYSTEM.....	496	.ALIMENTARY TRACT AND METABOLISM..... 85
<i>Aurozapine 30 (DO)</i>		<i>Aylide 4 (AF)</i>
.NERVOUS SYSTEM.....	572	.ALIMENTARY TRACT AND METABOLISM..... 85
<i>Aurozapine 45 (DO)</i>		AZACITIDINE
.NERVOUS SYSTEM.....	572	.Section 100..... 757, 1014
<i>Auscap Aspen (QA)</i>		<i>Azamun (GN)</i>
.NERVOUS SYSTEM.....	567	.ANTINEOPLASTIC AND IMMUNOMODULATING
<i>Ausfam 20 (QA)</i>		AGENTS 489
.ALIMENTARY TRACT AND METABOLISM.....	60	<i>Azapin (QA)</i>
<i>Ausfam 40 (QA)</i>		.ANTINEOPLASTIC AND IMMUNOMODULATING
.ALIMENTARY TRACT AND METABOLISM.....	61	AGENTS 489
<i>Ausgem (QA)</i>		<i>Azarga (AQ)</i>
.CARDIOVASCULAR SYSTEM.....	169	.SENSORY ORGANS..... 609, 610
<i>Auspril (QA)</i>		<i>Azastrole (ER)</i>
.CARDIOVASCULAR SYSTEM.....	135	.ANTINEOPLASTIC AND IMMUNOMODULATING
<i>Ausran (QA)</i>		AGENTS 297
		AZATHIOPRINE

GENERIC/PROPRIETARY INDEX

.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	489
<i>Azathioprine AN (EA)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	489
<i>Azathioprine GH (GQ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	489
<i>Azathioprine Sandoz (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	489
<i>Azilect (LU)</i>	
.NERVOUS SYSTEM.....	543
AZITHROMYCIN	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	237, 238
.Repatriation Schedule	1259
.Section 100	737, 993
.SENSORY ORGANS.....	605
<i>Azithromycin Sandoz (SZ)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	238
.Repatriation Schedule	1259
.SENSORY ORGANS.....	605
<i>Azithromycin-GA (UA)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	238
.Repatriation Schedule	1259
.SENSORY ORGANS.....	605
<i>Azol 100 (AF)</i>	
.GENITO URINARY SYSTEM AND SEX HORMONES .	211
<i>Azol 200 (AF)</i>	
.GENITO URINARY SYSTEM AND SEX HORMONES .	211
<i>Azopt (AQ)</i>	
.SENSORY ORGANS.....	609

B

BACILLUS CALMETTE AND GUERIN-CONNAUGHT STRAIN	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	303
BACILLUS CALMETTE AND GUERIN-TICE STRAIN	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	303
BACLOFEN	
.MUSCULO-SKELETAL SYSTEM	496
.Section 100	918, 1176
<i>Bactigras 7457 (SN)</i>	
.Repatriation Schedule	1280
<i>Bactrim (RO)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	237
<i>Bactrim DS (RO)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	237
<i>Bactroban (GK)</i>	
.Repatriation Schedule	1252
.RESPIRATORY SYSTEM	594
BALSALAZIDE	
.ALIMENTARY TRACT AND METABOLISM.....	78

BANDAGE ABSORBENT WOOL	
.Repatriation Schedule	1273
BANDAGE CALICO	
.Repatriation Schedule	1273
BANDAGE COMPRESSION	
.Repatriation Schedule	1273, 1274
BANDAGE RETENTION COHESIVE HEAVY	
.Repatriation Schedule	1274
BANDAGE RETENTION COHESIVE LIGHT	
.Repatriation Schedule	1274
BANDAGE RETENTION COTTON CREPE	
.Repatriation Schedule	1274
BANDAGE TUBULAR	
.Repatriation Schedule	1274, 1275
BANDAGE TUBULAR FINGER	
.Repatriation Schedule	1275
BANDAGE TUBULAR LIGHT WEIGHT	
.Repatriation Schedule	1275
BANDAGE TUBULAR LONG STOCKING	
.Repatriation Schedule	1275
BANDAGE TUBULAR SHORT STOCKING	
.Repatriation Schedule	1275
BANDAGE ZINC PASTE	
.Repatriation Schedule	1276
<i>Baraclude (BQ)</i>	
.Section 100.....	746, 1002
<i>Barbloc 5 (AF)</i>	
.CARDIOVASCULAR SYSTEM	128
<i>basecal 100 (VF)</i>	
.VARIOUS.....	656
<i>basecal 200 (VF)</i>	
.VARIOUS.....	656
<i>Baxter Healthcare Pty Ltd (BX)</i>	
.BLOOD AND BLOOD FORMING ORGANS.....	119, 120
.Repatriation Schedule	1248
BECLOMETHASONE	
.RESPIRATORY SYSTEM.....	600
BEE VENOM	
.VARIOUS.....	626
<i>BenPen (CS)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	227
.Prescriber Bag	56
BENZATHINE BENZYL PENICILLIN	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	227
BENZHEXOL	
.NERVOUS SYSTEM.....	538
<i>Benztrop (PL)</i>	
.NERVOUS SYSTEM.....	539
BENZTROPINE	
.NERVOUS SYSTEM.....	538
BENZYDAMINE	
.ALIMENTARY TRACT AND METABOLISM.....	60
.Palliative Care.....	662
BENZYL PENICILLIN	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	227

GENERIC/PROPRIETARY INDEX

<i>Beprol 10 (DO)</i>		<i>Biatain Adhesive 3420 (CT)</i>	
.CARDIOVASCULAR SYSTEM	129	.Repatriation Schedule	1281
<i>Beprol 2.5 (DO)</i>		<i>Biatain Adhesive 3423 (CT)</i>	
.CARDIOVASCULAR SYSTEM	129	.Repatriation Schedule	1281
<i>Beprol 5 (DO)</i>		<i>Biatain Ag 9622 (CT)</i>	
.CARDIOVASCULAR SYSTEM	129	.Repatriation Schedule	1286
<i>Betachek (NA)</i>		<i>Biatain Ag 9632 (CT)</i>	
.VARIOUS	630, 631	.Repatriation Schedule	1286
<i>Betachek G5 (NA)</i>		<i>Biatain Non-adhesive 3410 (CT)</i>	
.VARIOUS	630, 631	.Repatriation Schedule	1281
<i>Betadine Antiseptic Liquid (SW)</i>		<i>Biatain Non-adhesive 3413 (CT)</i>	
.Repatriation Schedule	1253	.Repatriation Schedule	1281
<i>Betaferon (BN)</i>		<i>Biaxig (AV)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING		.ANTIINFECTIVES FOR SYSTEMIC USE	239, 240
AGENTS	302	<i>Bicalox (ER)</i>	
BETAINE		.ANTINEOPLASTIC AND IMMUNOMODULATING	
.ALIMENTARY TRACT AND METABOLISM	102	AGENTS	295
BETAINE + POLYAMINOPROPYL BIGUANIDE		BICALUTAMIDE	
.Repatriation Schedule	1276	.ANTINEOPLASTIC AND IMMUNOMODULATING	
<i>Betaloc (AP)</i>		AGENTS	295
.CARDIOVASCULAR SYSTEM	130	<i>Bicalutamide AN (EA)</i>	
BETAMETHASONE ACETATE + BETAMETHASONE		.ANTINEOPLASTIC AND IMMUNOMODULATING	
SODIUM PHOSPHATE		AGENTS	295
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX		<i>Bicalutamide-GA (GN)</i>	
HORMONES AND INSULINS	215, 216	.ANTINEOPLASTIC AND IMMUNOMODULATING	
BETAMETHASONE DIPROPIONATE		AGENTS	295
.DERMATOLOGICALS	195	BICARBONATE	
BETAMETHASONE VALERATE		.GENITO URINARY SYSTEM AND SEX HORMONES .	212
.DERMATOLOGICALS	196	BICARBONATE + CITRATE + TARTARIC ACID	
.Repatriation Schedule	1253	.Repatriation Schedule	1257
<i>betaquik (VF)</i>		<i>Bicard 10 (QA)</i>	
.VARIOUS	633	.CARDIOVASCULAR SYSTEM	129
<i>Betavit (PP)</i>		<i>Bicard 2.5 (QA)</i>	
.ALIMENTARY TRACT AND METABOLISM	100	.CARDIOVASCULAR SYSTEM	129
.Repatriation Schedule	1246	<i>Bicard 5 (QA)</i>	
BETAXOLOL		.CARDIOVASCULAR SYSTEM	129
.SENSORY ORGANS	611	<i>Bicillin L-A (PF)</i>	
BETHANECHOL		.ANTIINFECTIVES FOR SYSTEMIC USE	227
.NERVOUS SYSTEM	584	<i>Bicor (AL)</i>	
<i>Betnovate (QA)</i>		.CARDIOVASCULAR SYSTEM	129
.Repatriation Schedule	1253	<i>Biltricide (BN)</i>	
<i>Betnovate 1/2 (QA)</i>		.ANTIPARASITIC PRODUCTS, INSECTICIDES AND	
.DERMATOLOGICALS	196	REPELLENTS	592
<i>Betnovate 1/5 (QA)</i>		BIMATOPROST	
.DERMATOLOGICALS	196	.SENSORY ORGANS	611
<i>Betoptic (AQ)</i>		BIMATOPROST + TIMOLOL	
.SENSORY ORGANS	611	.SENSORY ORGANS	611, 612
<i>Betoptic S (AQ)</i>		<i>Biodone Forte (MW)</i>	
.SENSORY ORGANS	611	.Section 100	1208
<i>BetoQuin (IQ)</i>		<i>Bion Tears (AQ)</i>	
.SENSORY ORGANS	611	.SENSORY ORGANS	621
<i>Bgramin (GN)</i>		<i>Bionime Rightest (QB)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE	225, 226	.VARIOUS	630, 631
<i>BGStar (SW)</i>		BIPERIDEN	
.VARIOUS	630, 631	.NERVOUS SYSTEM	538

GENERIC/PROPRIETARY INDEX

BISACODYL	
.ALIMENTARY TRACT AND METABOLISM.....	73, 75
.Palliative Care	662, 663, 665
<i>Bisalax (AS)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	73, 75
.Palliative Care	662, 663, 665
<i>Biso 10 (GN)</i>	
.CARDIOVASCULAR SYSTEM	129
<i>Biso 2.5 (GN)</i>	
.CARDIOVASCULAR SYSTEM	129
<i>Biso 5 (GN)</i>	
.CARDIOVASCULAR SYSTEM	129
BISOPROLOL	
.CARDIOVASCULAR SYSTEM	129
<i>Bisoprolol AN (EA)</i>	
.CARDIOVASCULAR SYSTEM	129
<i>Bisoprolol GH (GQ)</i>	
.CARDIOVASCULAR SYSTEM	129
<i>Bisoprolol Sandoz (SZ)</i>	
.CARDIOVASCULAR SYSTEM	129
<i>Bispro 10 (AF)</i>	
.CARDIOVASCULAR SYSTEM	129
<i>Bispro 2.5 (AF)</i>	
.CARDIOVASCULAR SYSTEM	129
<i>Bispro 5 (AF)</i>	
.CARDIOVASCULAR SYSTEM	129
BIVALIRUDIN	
.BLOOD AND BLOOD FORMING ORGANS	110
<i>Blooms the Chemist Amlodipine/Atorvastatin 10/10 (IB)</i>	
.CARDIOVASCULAR SYSTEM	189
<i>Blooms the Chemist Amlodipine/Atorvastatin 10/20 (IB)</i>	
.CARDIOVASCULAR SYSTEM	190
<i>Blooms the Chemist Amlodipine/Atorvastatin 10/40 (IB)</i>	
.CARDIOVASCULAR SYSTEM	190
<i>Blooms the Chemist Amlodipine/Atorvastatin 10/80 (IB)</i>	
.CARDIOVASCULAR SYSTEM	190
<i>Blooms the Chemist Amlodipine/Atorvastatin 5/10 (IB)</i>	
.CARDIOVASCULAR SYSTEM	190
<i>Blooms the Chemist Amlodipine/Atorvastatin 5/20 (IB)</i>	
.CARDIOVASCULAR SYSTEM	190
<i>Blooms the Chemist Amlodipine/Atorvastatin 5/40 (IB)</i>	
.CARDIOVASCULAR SYSTEM	191
<i>Blooms the Chemist Amlodipine/Atorvastatin 5/80 (IB)</i>	
.CARDIOVASCULAR SYSTEM	191
<i>Blooms the Chemist Atorvastatin (IB)</i>	
.CARDIOVASCULAR SYSTEM	156, 157, 158
<i>Blooms the Chemist Celecoxib (IB)</i>	
.MUSCULO-SKELETAL SYSTEM	495
<i>Blooms the Chemist Perindopril (IB)</i>	
.CARDIOVASCULAR SYSTEM	137
<i>Blooms the Chemist Rosuvastatin (IB)</i>	
.CARDIOVASCULAR SYSTEM ...	161, 162, 163, 164, 165
<i>Blooms the Chemist Venlafaxine XR (IB)</i>	
.NERVOUS SYSTEM.....	572, 573
BOCEPREVIR	
.Section 100.....	738, 994
<i>Bondronat (RO)</i>	
.MUSCULO-SKELETAL SYSTEM	499
.Section 100.....	918, 1176
<i>Bonefos (BN)</i>	
.MUSCULO-SKELETAL SYSTEM	499
<i>Bonefos 800 mg (BN)</i>	
.MUSCULO-SKELETAL SYSTEM	499
BOSENTAN	
.Section 100.....	692, 699, 947, 954
<i>Botox (AG)</i>	
.Section 100.....	1201
BOTULINUM TOXIN TYPE A	
.Section 100.....	1198
<i>Breo Ellipta 100/25 (GK)</i>	
.RESPIRATORY SYSTEM.....	599
<i>Breo Ellipta 200/25 (GK)</i>	
.RESPIRATORY SYSTEM.....	599
<i>Bretaris Genuair (FK)</i>	
.RESPIRATORY SYSTEM.....	601
<i>Brevinor (PF)</i>	
.GENITO URINARY SYSTEM AND SEX HORMONES .	202
<i>Brevinor-1 (PF)</i>	
.GENITO URINARY SYSTEM AND SEX HORMONES .	202
<i>Bricanyl (AP)</i>	
.RESPIRATORY SYSTEM.....	603
<i>Bricanyl Turbuhaler (AP)</i>	
.RESPIRATORY SYSTEM.....	595
<i>Brilinta (AP)</i>	
.BLOOD AND BLOOD FORMING ORGANS.....	109
BRIMONIDINE	
.SENSORY ORGANS.....	608
BRIMONIDINE + TIMOLOL	
.SENSORY ORGANS.....	608
BRINZOLAMIDE	
.SENSORY ORGANS.....	609
BRINZOLAMIDE + TIMOLOL	
.SENSORY ORGANS.....	609
<i>BrinzoQuin (IQ)</i>	
.SENSORY ORGANS.....	609
BROMAZEPAM	
.Repatriation Schedule	1264
BROMOCRIPTINE	
.GENITO URINARY SYSTEM AND SEX HORMONES 200,	201
.NERVOUS SYSTEM.....	540
<i>bronchitol (XA)</i>	
.Section 100.....	929, 1192
<i>Brufen (GO)</i>	
.MUSCULO-SKELETAL SYSTEM	493
.Palliative Care.....	668, 669
<i>BSN 2902165 (BV)</i>	
.Repatriation Schedule	1286
<i>Budamax Aqueous (PM)</i>	
.Repatriation Schedule	1267

GENERIC/PROPRIETARY INDEX

<i>Budenofalk (OA)</i>		.CARDIOVASCULAR SYSTEM	191
.ALIMENTARY TRACT AND METABOLISM.....	77	<i>Cadatin 5/40 (FZ)</i>	
BUDESONIDE		.CARDIOVASCULAR SYSTEM	191
.ALIMENTARY TRACT AND METABOLISM.....	77	<i>Cadatin 5/80 (FZ)</i>	
.Repatriation Schedule.....	1267	.CARDIOVASCULAR SYSTEM	191
.RESPIRATORY SYSTEM	600	CADEXOMER-IODINE	
BUDESONIDE + EFORMOTEROL		.Repatriation Schedule	1276
.RESPIRATORY SYSTEM	595, 596	<i>Cadivast 10/10 (AF)</i>	
BUPRENORPHINE		.CARDIOVASCULAR SYSTEM	189
.NERVOUS SYSTEM.....	520	<i>Cadivast 10/20 (AF)</i>	
.Section 100	1208	.CARDIOVASCULAR SYSTEM	190
BUPRENORPHINE + NALOXONE		<i>Cadivast 10/40 (AF)</i>	
.Section 100	1208	.CARDIOVASCULAR SYSTEM	190
BUPROPION		<i>Cadivast 10/80 (AF)</i>	
.NERVOUS SYSTEM.....	584	.CARDIOVASCULAR SYSTEM	190
<i>Buscopan (BY)</i>		<i>Cadivast 5/10 (AF)</i>	
.Palliative Care	662	.CARDIOVASCULAR SYSTEM	190
.Prescriber Bag	57	<i>Cadivast 5/20 (AF)</i>	
.Repatriation Schedule	1244	.CARDIOVASCULAR SYSTEM	191
<i>Buspar (QA)</i>		<i>Cadivast 5/40 (AF)</i>	
.Repatriation Schedule	1264	.CARDIOVASCULAR SYSTEM	191
BUSPIRONE		<i>Cadivast 5/80 (AF)</i>	
.Repatriation Schedule	1264	.CARDIOVASCULAR SYSTEM	191
BUSULFAN		<i>Caduet 10/10 (PF)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING		.CARDIOVASCULAR SYSTEM	189
AGENTS	256	<i>Caduet 10/20 (PF)</i>	
<i>Butamol 2.5 (QA)</i>		.CARDIOVASCULAR SYSTEM	190
.Prescriber Bag	57	<i>Caduet 10/40 (PF)</i>	
.RESPIRATORY SYSTEM	594	.CARDIOVASCULAR SYSTEM	190
<i>Butamol 5 (QA)</i>		<i>Caduet 10/80 (PF)</i>	
.Prescriber Bag	57	.CARDIOVASCULAR SYSTEM	190
.RESPIRATORY SYSTEM	595	<i>Caduet 5/10 (PF)</i>	
<i>Byetta 10 microgram (AP)</i>		.CARDIOVASCULAR SYSTEM	190
.ALIMENTARY TRACT AND METABOLISM.....	100	<i>Caduet 5/20 (PF)</i>	
<i>Byetta 5 microgram (AP)</i>		.CARDIOVASCULAR SYSTEM	191
.ALIMENTARY TRACT AND METABOLISM.....	100	<i>Caduet 5/40 (PF)</i>	
		.CARDIOVASCULAR SYSTEM	191
		<i>Caduet 5/80 (PF)</i>	
		.CARDIOVASCULAR SYSTEM	191
		<i>Caelyx (JC)</i>	
		.Section 100.....	758, 1015
		<i>Cal-500 (PP)</i>	
		.ALIMENTARY TRACT AND METABOLISM.....	101
		.Repatriation Schedule	1246
		<i>CAL-600 (PP)</i>	
		.Repatriation Schedule	1246
		CALCIPTRIOL	
		.DERMATOLOGICALS	193
		CALCIPTRIOL + BETAMETHASONE DIPROPIONATE	
		.DERMATOLOGICALS	193, 194
		<i>Calciprox (ER)</i>	
		.ALIMENTARY TRACT AND METABOLISM.....	100
		.MUSCULO-SKELETAL SYSTEM	506
		<i>Calci-Tab 600 (AE)</i>	
		.ALIMENTARY TRACT AND METABOLISM.....	101

C

GENERIC/PROPRIETARY INDEX

CALCITRIOL		
.ALIMENTARY TRACT AND METABOLISM.....	100	
.MUSCULO-SKELETAL SYSTEM	506	
<i>Calcitriol AN (EA)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	100	
.MUSCULO-SKELETAL SYSTEM	506	
<i>Calcitriol Sandoz (SZ)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	100	
.MUSCULO-SKELETAL SYSTEM	506	
<i>Calcitriol-GA (UA)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	100	
.MUSCULO-SKELETAL SYSTEM	506	
CALCIUM		
.ALIMENTARY TRACT AND METABOLISM.....	101	
.Repatriation Schedule.....	1246	
CALCIUM CARBONATE + GLYCINE		
.Repatriation Schedule.....	1244	
<i>Calcium Folate Ebewe (SZ)</i>		
.VARIOUS.....	627, 628	
<i>Calmurid (OL)</i>		
.Repatriation Schedule.....	1251	
<i>Cal-Sup (IA)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	101	
.Repatriation Schedule.....	1246	
<i>Calutex (QA)</i>		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	295	
<i>Camino Pro Bettermilk (QH)</i>		
.VARIOUS.....	657	
<i>Camino Pro Complete (QH)</i>		
.VARIOUS.....	657	
<i>Camino Pro Restore (QH)</i>		
.VARIOUS.....	657	
<i>Campral (AF)</i>		
.NERVOUS SYSTEM.....	588	
CANAGLIFLOZIN		
.ALIMENTARY TRACT AND METABOLISM.....	96	
CANDESARTAN		
.CARDIOVASCULAR SYSTEM	143	
CANDESARTAN + HYDROCHLOROTHIAZIDE		
.CARDIOVASCULAR SYSTEM	147	
<i>Candesartan AN (EA)</i>		
.CARDIOVASCULAR SYSTEM	143, 144	
<i>Candesartan Aspen 16 (QA)</i>		
.CARDIOVASCULAR SYSTEM	144	
<i>Candesartan Aspen 32 (QA)</i>		
.CARDIOVASCULAR SYSTEM	144	
<i>Candesartan Aspen 4 (QA)</i>		
.CARDIOVASCULAR SYSTEM	144	
<i>Candesartan Aspen 8 (QA)</i>		
.CARDIOVASCULAR SYSTEM	144	
<i>Candesartan Combi Aspen 16/12.5 (QA)</i>		
.CARDIOVASCULAR SYSTEM	147	
<i>Candesartan Combi Aspen 32/12.5 (QA)</i>		
.CARDIOVASCULAR SYSTEM	148	
<i>Candesartan Combi Aspen 32/25 (QA)</i>		
.CARDIOVASCULAR SYSTEM	148	
<i>Candesartan GH (GQ)</i>		
.CARDIOVASCULAR SYSTEM	144	
<i>Candesartan HCT GH 16/12.5 (GQ)</i>		
.CARDIOVASCULAR SYSTEM	147	
<i>Candesartan HCT GH 32/12.5 (GQ)</i>		
.CARDIOVASCULAR SYSTEM	148	
<i>Candesartan HCT GH 32/25 (GQ)</i>		
.CARDIOVASCULAR SYSTEM	148	
<i>Candesartan HCTZ AN 16/12.5 (EA)</i>		
.CARDIOVASCULAR SYSTEM	147	
<i>Candesartan HCTZ AN 32/12.5 (EA)</i>		
.CARDIOVASCULAR SYSTEM	148	
<i>Candesartan HCTZ AN 32/25 (EA)</i>		
.CARDIOVASCULAR SYSTEM	148	
<i>Candesartan HCTZ RBX 16/12.5 (RA)</i>		
.CARDIOVASCULAR SYSTEM	147	
<i>Candesartan HCTZ RBX 32/12.5 (RA)</i>		
.CARDIOVASCULAR SYSTEM	148	
<i>Candesartan HCTZ RBX 32/25 (RA)</i>		
.CARDIOVASCULAR SYSTEM	148	
<i>Candesartan HCTZ-GA 16/12.5 (GN)</i>		
.CARDIOVASCULAR SYSTEM	147	
<i>Candesartan HCTZ-GA 32/12.5 (GN)</i>		
.CARDIOVASCULAR SYSTEM	148	
<i>Candesartan HCTZ-GA 32/25 (GN)</i>		
.CARDIOVASCULAR SYSTEM	148	
<i>Candesartan RBX (RA)</i>		
.CARDIOVASCULAR SYSTEM	144	
<i>Candesartan Sandoz (SZ)</i>		
.CARDIOVASCULAR SYSTEM	144	
<i>Candesartan/HCT Sandoz (SZ)</i>		
.CARDIOVASCULAR SYSTEM	147, 148	
<i>Candesartan-GA (GN)</i>		
.CARDIOVASCULAR SYSTEM	144	
CAPECITABINE		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	258	
<i>Capecitabine Actavis (GN)</i>		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	258	
<i>Capecitabine Alphapharm (AF)</i>		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	258	
<i>Capecitabine AN (EA)</i>		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	258	
<i>Capecitabine Apotex (TX)</i>		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	258	
<i>Capecitabine GH (GQ)</i>		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	258	
<i>Capecitabine Sandoz (SZ)</i>		

GENERIC/PROPRIETARY INDEX

.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	258
<i>Capecitabine-DRLA (RZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	258
<i>Capoten (QA)</i>	
.CARDIOVASCULAR SYSTEM	134, 135
CAPTOPRIL	
.CARDIOVASCULAR SYSTEM	134, 135
<i>Captopril Sandoz (SZ)</i>	
.CARDIOVASCULAR SYSTEM	134
<i>Carafate (AS)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	67
CARBAMAZEPINE	
.NERVOUS SYSTEM.....	529, 530
<i>Carbamazepine Sandoz (SZ)</i>	
.NERVOUS SYSTEM.....	529
CARBAMIDE PEROXIDE	
.Repatriation Schedule	1269
<i>Carbimazol ARISTO (PQ)</i>	
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS.....	220
CARBIMAZOLE	
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS.....	219
<i>CarboFLEX 403202 (CC)</i>	
.Repatriation Schedule	1276
<i>CarboFLEX 403204 (CC)</i>	
.Repatriation Schedule	1277
<i>Carbohydrate Free Mixture (SB)</i>	
.VARIOUS.....	658
CARBOHYDRATE, FAT, VITAMINS, MINERALS AND TRACE ELEMENTS	
.VARIOUS.....	655
CARBOHYDRATES, FAT, VITAMINS, MINERALS, TRACE ELEMENTS AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID	
.VARIOUS.....	656
CARBOMER-974	
.SENSORY ORGANS.....	618
CARBOMER-980	
.SENSORY ORGANS.....	618, 619
<i>carbzero (VF)</i>	
.VARIOUS.....	632
<i>Cardiprin 100 (RC)</i>	
.Repatriation Schedule	1248
<i>Cardizem (SW)</i>	
.CARDIOVASCULAR SYSTEM	134
<i>Cardizem CD (SW)</i>	
.CARDIOVASCULAR SYSTEM	134
<i>Cardol (AF)</i>	
.CARDIOVASCULAR SYSTEM	122
<i>CareSens (PB)</i>	
.VARIOUS.....	630, 631
<i>CareSens N (PB)</i>	
.VARIOUS.....	630, 631
CARMELLOSE SODIUM	
.SENSORY ORGANS.....	619
CARMELLOSE SODIUM + GELATIN + PECTIN	
.Repatriation Schedule	1251
CARMELLOSE SODIUM + GLYCEROL	
.SENSORY ORGANS.....	620
CARMUSTINE	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	256
<i>Cartia (AS)</i>	
.Repatriation Schedule	1248
CARVEDILOL	
.CARDIOVASCULAR SYSTEM	131
<i>Carvedilol AN (EA)</i>	
.CARDIOVASCULAR SYSTEM	131
<i>Carvedilol generichealth (GQ)</i>	
.CARDIOVASCULAR SYSTEM	131
<i>Carvedilol Sandoz (SZ)</i>	
.CARDIOVASCULAR SYSTEM	131
<i>Catapres (BY)</i>	
.CARDIOVASCULAR SYSTEM	125
<i>Catapres 100 (BY)</i>	
.CARDIOVASCULAR SYSTEM	125
<i>Caverject (PF)</i>	
.Repatriation Schedule	1256
<i>Cavicare 4563 (SN)</i>	
.Repatriation Schedule	1278
<i>Cavstat (AF)</i>	
.CARDIOVASCULAR SYSTEM ...	161, 162, 163, 164, 165
<i>Ceclor (AS)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	234
<i>Ceclor CD (AS)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	234, 235
CEFACLOR	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	234
<i>Cefaclor GH (GQ)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	234
<i>Cefaclor-GA (GN)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	234
<i>Cefalexin Sandoz (SZ)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	231, 232
<i>Cefazolin Sandoz (SZ)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	233, 234
<i>Cefazolin-AFT (AE)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	233, 234
CEFEPIME	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	237
<i>Cefepime Alphapharm (AF)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	237
<i>Cefepime Sandoz (SZ)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	237
<i>Cefepime-AFT (AE)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	237
CEFOTAXIME	

GENERIC/PROPRIETARY INDEX

.ANTIINFECTIVES FOR SYSTEMIC USE.....	235, 236
<i>Cefotaxime Sandoz (SZ)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	235, 236
CEFTRIAXONE	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	236
<i>Ceftriaxone Alphapharm (AF)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	236
<i>Ceftriaxone ICP (PP)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	236, 237
<i>Ceftriaxone Sandoz (SZ)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	236
<i>Ceftriaxone-AFT (AE)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	236
CEFUROXIME	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	235
<i>Celapram (AF)</i>	
.NERVOUS SYSTEM.....	564, 565
<i>Celaxib (AF)</i>	
.MUSCULO-SKELETAL SYSTEM	495
<i>Celebrex (PF)</i>	
.MUSCULO-SKELETAL SYSTEM	495
CELECOXIB	
.MUSCULO-SKELETAL SYSTEM	494
<i>Celecoxib Actavis (GN)</i>	
.MUSCULO-SKELETAL SYSTEM	495
<i>Celecoxib AN (EA)</i>	
.MUSCULO-SKELETAL SYSTEM	495
<i>Celecoxib GH (GQ)</i>	
.MUSCULO-SKELETAL SYSTEM	495
<i>Celecoxib RBX (RA)</i>	
.MUSCULO-SKELETAL SYSTEM	495
<i>Celecoxib Sandoz (SZ)</i>	
.MUSCULO-SKELETAL SYSTEM	495
<i>Celestone Chronodose (MK)</i>	
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS.....	216
<i>Celestone-M (MK)</i>	
.DERMATOLOGICALS.....	196
<i>Celxi (QA)</i>	
.MUSCULO-SKELETAL SYSTEM	495
<i>Celica (RA)</i>	
.NERVOUS SYSTEM.....	564
<i>CellCept (RO)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	316
.Section 100	802, 803, 1061
<i>Cellufresh (AG)</i>	
.SENSORY ORGANS.....	619, 620
<i>Celluvisc (AG)</i>	
.SENSORY ORGANS.....	619
<i>Celsentri (VI)</i>	
.Section 100	755, 1012
<i>Cephalex 250 (CR)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	231, 232
<i>Cephalex 500 (NJ)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	232
CEPHALEXIN	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	231, 232
<i>Cephalexin AN (EA)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	231, 232
<i>Cephalexin generichealth (GQ)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	231, 232
CEPHALOTHIN	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	233
CEPHAZOLIN	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	233
<i>Cephazolin Alphapharm (AF)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	233, 234
<i>Ceptolate (AF)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	316
.Section 100.....	802, 803, 1060, 1061
<i>Certican (NV)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	315
.Section 100.....	802, 1060
CERTOLIZUMAB PEGOL	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	375, 381, 392
<i>Cerumol (UN)</i>	
.Repatriation Schedule	1269
CETIRIZINE	
.Repatriation Schedule	1268
CETRORELIX	
.Section 100.....	1205
<i>Cetrotide (SG)</i>	
.Section 100.....	1205
<i>C-Flox 250 (AL)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	242
<i>C-Flox 500 (AL)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	242
<i>C-Flox 750 (AL)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	243
<i>Champix (PF)</i>	
.NERVOUS SYSTEM.....	587, 588
<i>Chem mart Aciclovir (CH)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	250
<i>Chem mart Alendronate 70mg (CH)</i>	
.MUSCULO-SKELETAL SYSTEM	498
<i>Chem mart Allopurinol (CH)</i>	
.MUSCULO-SKELETAL SYSTEM	497
<i>Chem mart Alprazolam (CH)</i>	
.NERVOUS SYSTEM.....	560
<i>Chem mart Amiodarone (CH)</i>	
.CARDIOVASCULAR SYSTEM	122
<i>Chem mart Amitriptyline (CH)</i>	
.NERVOUS SYSTEM.....	563
<i>Chem mart Amlodipine (CH)</i>	
.CARDIOVASCULAR SYSTEM	132
<i>Chem mart Amlodipine/Atorvastatin 10/10 (CH)</i>	

GENERIC/PROPRIETARY INDEX

.CARDIOVASCULAR SYSTEM	189	.ANTIINFECTIVES FOR SYSTEMIC USE	231, 232, 233
<i>Chem mart Amlodipine/Atorvastatin 10/20 (CH)</i>		<i>Chem mart Citalopram (CH)</i>	
.CARDIOVASCULAR SYSTEM	190	.NERVOUS SYSTEM	564
<i>Chem mart Amlodipine/Atorvastatin 10/40 (CH)</i>		<i>Chem mart Clarithromycin (CH)</i>	
.CARDIOVASCULAR SYSTEM	190	.ANTIINFECTIVES FOR SYSTEMIC USE	238
<i>Chem mart Amlodipine/Atorvastatin 10/80 (CH)</i>		<i>Chem mart Clindamycin (CH)</i>	
.CARDIOVASCULAR SYSTEM	190	.ANTIINFECTIVES FOR SYSTEMIC USE	240
<i>Chem mart Amlodipine/Atorvastatin 5/10 (CH)</i>		<i>Chem mart Clomipramine (CH)</i>	
.CARDIOVASCULAR SYSTEM	190	.NERVOUS SYSTEM	563
<i>Chem mart Amlodipine/Atorvastatin 5/20 (CH)</i>		<i>Chem mart Clopidogrel (CH)</i>	
.CARDIOVASCULAR SYSTEM	191	.BLOOD AND BLOOD FORMING ORGANS	107
<i>Chem mart Amlodipine/Atorvastatin 5/40 (CH)</i>		.Repatriation Schedule	1248
.CARDIOVASCULAR SYSTEM	191	<i>Chem mart Clopidogrel/Aspirin 75/100 (CH)</i>	
<i>Chem mart Amlodipine/Atorvastatin 5/80 (CH)</i>		.BLOOD AND BLOOD FORMING ORGANS	108
.CARDIOVASCULAR SYSTEM	191	<i>Chem mart Diclofenac (CH)</i>	
<i>Chem mart Amoxicillin (CH)</i>		.MUSCULO-SKELETAL SYSTEM	490
.ANTIINFECTIVES FOR SYSTEMIC USE	225, 226	.Palliative Care	667, 668
<i>Chem mart Amoxicillin and Clavulanic Acid (CH)</i>		<i>Chem mart Diltiazem CD (CH)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE	230	.CARDIOVASCULAR SYSTEM	134
<i>Chem mart Anastrozole (CH)</i>		<i>Chem mart Donepezil (CH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING		.NERVOUS SYSTEM	576, 577, 578
AGENTS	297	<i>Chem mart Doxycycline (CH)</i>	
<i>Chem mart Atenolol (CH)</i>		.ANTIINFECTIVES FOR SYSTEMIC USE	223, 224
.CARDIOVASCULAR SYSTEM	128	<i>Chem mart Duloxetine (CH)</i>	
<i>Chem mart Atorvastatin (CH)</i>		.NERVOUS SYSTEM	570, 571
.CARDIOVASCULAR SYSTEM	156, 157, 158, 159	<i>Chem mart Enalapril (CH)</i>	
<i>Chem mart Azithromycin (CH)</i>		.CARDIOVASCULAR SYSTEM	135
.ANTIINFECTIVES FOR SYSTEMIC USE	238	<i>Chem mart Escitalopram (CH)</i>	
.Repatriation Schedule	1259	.NERVOUS SYSTEM	565
.SENSORY ORGANS	605	<i>Chem mart Famciclovir (CH)</i>	
<i>Chem mart Baclofen (CH)</i>		.ANTIINFECTIVES FOR SYSTEMIC USE	252, 253
.MUSCULO-SKELETAL SYSTEM	496	<i>Chem mart Famotidine (CH)</i>	
<i>Chem mart Bisoprolol (CH)</i>		.ALIMENTARY TRACT AND METABOLISM	60, 61
.CARDIOVASCULAR SYSTEM	129	<i>Chem mart Fluoxetine (CH)</i>	
<i>Chem mart Candesartan (CH)</i>		.NERVOUS SYSTEM	567
.CARDIOVASCULAR SYSTEM	144	<i>Chem mart Furosemide (CH)</i>	
<i>Chem mart Candesartan HCTZ 16/12.5 (CH)</i>		.CARDIOVASCULAR SYSTEM	126, 127
.CARDIOVASCULAR SYSTEM	147	<i>Chem mart Gemfibrozil (CH)</i>	
<i>Chem mart Candesartan HCTZ 32/12.5 (CH)</i>		.CARDIOVASCULAR SYSTEM	169
.CARDIOVASCULAR SYSTEM	148	<i>Chem mart Glimepiride (CH)</i>	
<i>Chem mart Candesartan HCTZ 32/25 (CH)</i>		.ALIMENTARY TRACT AND METABOLISM	84
.CARDIOVASCULAR SYSTEM	148	<i>Chem mart Glimepiride MR (CH)</i>	
<i>Chem mart Carvedilol 12.5 mg (CH)</i>		.ALIMENTARY TRACT AND METABOLISM	84
.CARDIOVASCULAR SYSTEM	131	<i>Chem mart Hydroxychloroquine (CH)</i>	
<i>Chem mart Carvedilol 25 mg (CH)</i>		.MUSCULO-SKELETAL SYSTEM	495
.CARDIOVASCULAR SYSTEM	131	<i>Chem mart Indapamide (CH)</i>	
<i>Chem mart Carvedilol 3.125 mg (CH)</i>		.CARDIOVASCULAR SYSTEM	126
.CARDIOVASCULAR SYSTEM	131	<i>Chem mart Indapamide SR (CH)</i>	
<i>Chem mart Carvedilol 6.25 mg (CH)</i>		.CARDIOVASCULAR SYSTEM	126
.CARDIOVASCULAR SYSTEM	131	<i>Chem mart Irbesartan (CH)</i>	
<i>Chem mart Cefaclor CD (CH)</i>		.CARDIOVASCULAR SYSTEM	145
.ANTIINFECTIVES FOR SYSTEMIC USE	234	<i>Chem mart Irbesartan HCTZ (CH)</i>	
<i>Chem mart Celecoxib (CH)</i>		.CARDIOVASCULAR SYSTEM	149
.MUSCULO-SKELETAL SYSTEM	495	<i>Chem mart Isosorbide Mononitrate (CH)</i>	
<i>Chem mart Cephalexin (CH)</i>		.CARDIOVASCULAR SYSTEM	123

GENERIC/PROPRIETARY INDEX

<i>Chem mart Latanoprost (CH)</i>		<i>Chem mart Rabeprazole (CH)</i>	
.SENSORY ORGANS.....	612	.ALIMENTARY TRACT AND METABOLISM.....	66
<i>Chem mart Lercanidipine (CH)</i>		<i>Chem mart Raloxifene (CH)</i>	
.CARDIOVASCULAR SYSTEM.....	133	.MUSCULO-SKELETAL SYSTEM	508
<i>Chem mart Letrozole (CH)</i>		<i>Chem mart Ramipril (CH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING		.CARDIOVASCULAR SYSTEM	138, 139, 140
AGENTS	298	<i>Chem mart Ranitidine (CH)</i>	
<i>Chem mart Levetiracetam (CH)</i>		.ALIMENTARY TRACT AND METABOLISM.....	61
.NERVOUS SYSTEM.....	535	<i>Chem mart Risedronate (CH)</i>	
<i>Chem mart Lisinopril (CH)</i>		.MUSCULO-SKELETAL SYSTEM	500
.CARDIOVASCULAR SYSTEM.....	136	<i>Chem mart Rosuvastatin (CH)</i>	
<i>Chem mart Meloxicam (CH)</i>		.CARDIOVASCULAR SYSTEM ...	161, 162, 163, 164, 165
.MUSCULO-SKELETAL SYSTEM	491, 492	<i>Chem mart Roxithromycin (CH)</i>	
<i>Chem mart Meloxicam 15 mg (CH)</i>		.ANTIINFECTIVES FOR SYSTEMIC USE.....	239, 240
.MUSCULO-SKELETAL SYSTEM	491	<i>Chem mart Sertraline (CH)</i>	
<i>Chem mart Meloxicam 7.5 mg (CH)</i>		.NERVOUS SYSTEM.....	568
.MUSCULO-SKELETAL SYSTEM	492	<i>Chem mart Sildenafil (CH)</i>	
<i>Chem mart Metformin (CH)</i>		.Repatriation Schedule	1256
.ALIMENTARY TRACT AND METABOLISM.....	83, 84	<i>Chem mart Simvastatin (CH)</i>	
<i>Chem mart Metformin 1000 (CH)</i>		.CARDIOVASCULAR SYSTEM	166, 167, 168
.ALIMENTARY TRACT AND METABOLISM.....	83	<i>Chem mart Sotalol (CH)</i>	
<i>Chem mart Metformin XR 500 (CH)</i>		.CARDIOVASCULAR SYSTEM	122
.ALIMENTARY TRACT AND METABOLISM.....	84	<i>Chem mart Sumatriptan (CH)</i>	
<i>Chem mart Metoprolol (CH)</i>		.NERVOUS SYSTEM.....	526
.CARDIOVASCULAR SYSTEM	130	<i>Chem mart Telmisartan (CH)</i>	
<i>Chem mart Mirtazapine (CH)</i>		.CARDIOVASCULAR SYSTEM	146
.NERVOUS SYSTEM.....	572	<i>Chem mart Telmisartan HCTZ 40/12.5 (CH)</i>	
<i>Chem mart Moclobemide (CH)</i>		.CARDIOVASCULAR SYSTEM	150
.NERVOUS SYSTEM.....	569	<i>Chem mart Telmisartan HCTZ 80/12.5 (CH)</i>	
<i>Chem mart Montelukast (CH)</i>		.CARDIOVASCULAR SYSTEM	150
.RESPIRATORY SYSTEM	603, 604	<i>Chem mart Telmisartan HCTZ 80/25 (CH)</i>	
<i>Chem mart Olanzapine (CH)</i>		.CARDIOVASCULAR SYSTEM	151
.NERVOUS SYSTEM.....	547, 549, 550, 551	<i>Chem mart Tramadol (CH)</i>	
<i>Chem mart Olanzapine ODT (CH)</i>		.NERVOUS SYSTEM.....	522, 523
.NERVOUS SYSTEM.....	546, 548, 549	<i>Chem mart Tramadol SR (CH)</i>	
<i>Chem mart Omeprazole (CH)</i>		.NERVOUS SYSTEM.....	521
.ALIMENTARY TRACT AND METABOLISM.....	64	<i>Chem mart Valaciclovir (CH)</i>	
<i>Chem mart Pantoprazole (CH)</i>		.ANTIINFECTIVES FOR SYSTEMIC USE.....	253, 254
.ALIMENTARY TRACT AND METABOLISM.....	65	<i>Chem mart Venlafaxine XR (CH)</i>	
<i>Chem mart Paroxetine (CH)</i>		.NERVOUS SYSTEM.....	572, 573
.NERVOUS SYSTEM.....	568	CHLORAMBUCIL	
<i>Chem mart Perindopril (CH)</i>		.ANTINEOPLASTIC AND IMMUNOMODULATING	
.CARDIOVASCULAR SYSTEM	137	AGENTS	256
<i>Chem mart Perindopril/ Indapamide 4/1.25 (CH)</i>		CHLORAMPHENICOL	
.CARDIOVASCULAR SYSTEM	141	.SENSORY ORGANS.....	605, 624
<i>Chem mart Pioglitazone (CH)</i>		CHLORHEXIDINE	
.ALIMENTARY TRACT AND METABOLISM.....	92	.Repatriation Schedule	1244
<i>Chem mart Piroxicam (CH)</i>		<i>Chloromycetin (PF)</i>	
.MUSCULO-SKELETAL SYSTEM	492	.SENSORY ORGANS.....	624
<i>Chem mart Pravastatin (CH)</i>		CHLORPROMAZINE	
.CARDIOVASCULAR SYSTEM	159, 160, 161	.NERVOUS SYSTEM.....	543
<i>Chem mart Prazosin (CH)</i>		<i>Chlorsig (QA)</i>	
.CARDIOVASCULAR SYSTEM	125	.SENSORY ORGANS.....	605
<i>Chem mart Quetiapine (CH)</i>		CHLORTHALIDONE	
.NERVOUS SYSTEM.....	552, 553, 554	.CARDIOVASCULAR SYSTEM	126

GENERIC/PROPRIETARY INDEX

<i>Chlorvescent (AS)</i>		.ANTIINFECTIVES FOR SYSTEMIC USE.....	242
.ALIMENTARY TRACT AND METABOLISM.....	101	.SENSORY ORGANS.....	606, 624
CHOLESTYRAMINE		<i>Ciprofloxacin 500 (CR)</i>	
.CARDIOVASCULAR SYSTEM.....	169, 170	.ANTIINFECTIVES FOR SYSTEMIC USE.....	242
<i>Cholstat 10 (AF)</i>		<i>Ciprofloxacin 750 (CR)</i>	
.CARDIOVASCULAR SYSTEM.....	159, 160	.ANTIINFECTIVES FOR SYSTEMIC USE.....	243
<i>Cholstat 20 (AF)</i>		<i>Ciprofloxacin AN (EA)</i>	
.CARDIOVASCULAR SYSTEM.....	159, 161	.ANTIINFECTIVES FOR SYSTEMIC USE.....	242, 243
<i>Cholstat 40 (AF)</i>		<i>Ciprofloxacin Sandoz (SZ)</i>	
.CARDIOVASCULAR SYSTEM.....	160, 161	.ANTIINFECTIVES FOR SYSTEMIC USE.....	242, 243
<i>Cholvastin (RA)</i>		<i>Ciprofloxacin-BW (GQ)</i>	
.CARDIOVASCULAR SYSTEM.....	159, 160, 161	.ANTIINFECTIVES FOR SYSTEMIC USE.....	242, 243
CHORIOGONADOTROPIN ALFA		<i>Ciprofloxacin-DRLA (RZ)</i>	
.Section 100	1205	.ANTIINFECTIVES FOR SYSTEMIC USE.....	242, 243
<i>Cialis (LY)</i>		<i>Ciprofloxacin-GA (GN)</i>	
.Repatriation Schedule.....	1257	.ANTIINFECTIVES FOR SYSTEMIC USE.....	242, 243
<i>Ciazil (UA)</i>		<i>Ciprol 250 (QA)</i>	
.NERVOUS SYSTEM.....	564	.ANTIINFECTIVES FOR SYSTEMIC USE.....	242
CICLESONIDE		<i>Ciprol 500 (QA)</i>	
.RESPIRATORY SYSTEM	601	.ANTIINFECTIVES FOR SYSTEMIC USE.....	242
CICLOPIROX		<i>Ciprol 750 (QA)</i>	
.Repatriation Schedule.....	1250	.ANTIINFECTIVES FOR SYSTEMIC USE.....	243
<i>Cifran (RA)</i>		<i>Ciproxin 250 (BN)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	242, 243	.ANTIINFECTIVES FOR SYSTEMIC USE.....	242
<i>Cilamox (QA)</i>		<i>Ciproxin 500 (BN)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	225, 226	.ANTIINFECTIVES FOR SYSTEMIC USE.....	242
<i>Cilex (GN)</i>		<i>Ciproxin 750 (BN)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	231, 232, 233	.ANTIINFECTIVES FOR SYSTEMIC USE.....	243
<i>Cilicaine (QA)</i>		CITALOPRAM	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	228	.NERVOUS SYSTEM.....	564
.Prescriber Bag	56	<i>Citalopram Actavis (UA)</i>	
<i>Cilicaine V (FM)</i>		.NERVOUS SYSTEM.....	564
.ANTIINFECTIVES FOR SYSTEMIC USE.....	227	<i>Citalopram Actavis (VN)</i>	
<i>Cilicaine VK (FM)</i>		.NERVOUS SYSTEM.....	564, 565
.ANTIINFECTIVES FOR SYSTEMIC USE.....	227, 228	<i>Citalopram AN (EA)</i>	
<i>Cilopam-S (ER)</i>		.NERVOUS SYSTEM.....	564, 565
.NERVOUS SYSTEM.....	565	<i>Citalopram generichealth (GQ)</i>	
<i>Cilopen VK (GN)</i>		.NERVOUS SYSTEM.....	564
.ANTIINFECTIVES FOR SYSTEMIC USE.....	227, 228	<i>Citalopram Sandoz (SZ)</i>	
<i>CiloQuin (IQ)</i>		.NERVOUS SYSTEM.....	564, 565
.SENSORY ORGANS.....	606	<i>Citalopram-GA (GN)</i>	
<i>Ciloxan (AQ)</i>		.NERVOUS SYSTEM.....	564, 565
.SENSORY ORGANS.....	606, 624	<i>Citrulline 1000 (VF)</i>	
CIMETIDINE		.VARIOUS.....	656
.ALIMENTARY TRACT AND METABOLISM.....	60	CITRULLINE WITH CARBOHYDRATE	
<i>Cimzia (UC)</i>		.VARIOUS.....	656
.ANTINEOPLASTIC AND IMMUNOMODULATING		<i>Clamoxyl (AL)</i>	
AGENTS	381, 392, 402	.ANTIINFECTIVES FOR SYSTEMIC USE.....	229
CINACALCET		<i>Clamoxyl Duo (AL)</i>	
.Section 100	736, 991	.ANTIINFECTIVES FOR SYSTEMIC USE.....	229, 230
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX		<i>Clamoxyl Duo 400 (AL)</i>	
HORMONES AND INSULINS.....	221	.ANTIINFECTIVES FOR SYSTEMIC USE.....	229
<i>Cipramil (LU)</i>		<i>Clamoxyl Duo forte (AL)</i>	
.NERVOUS SYSTEM.....	564	.ANTIINFECTIVES FOR SYSTEMIC USE.....	230
CIPROFLOXACIN		<i>Clarac (GN)</i>	

GENERIC/PROPRIETARY INDEX

.ANTIINFECTIVES FOR SYSTEMIC USE.....	238
<i>Claratyne (BN)</i>	
.Repatriation Schedule.....	1268
<i>Clarithexal (HX)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	238
<i>Clarithro 250 (QA)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	238
CLARITHROMYCIN	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	238
.Section 100	737, 993
<i>Clarithromycin AN (EA)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	238
<i>Clarithromycin Sandoz (SZ)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	238
<i>Clavam 875 mg/125 mg (NJ)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	230
<i>Cleocin (FZ)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	240
<i>Clexane (SW)</i>	
.BLOOD AND BLOOD FORMING ORGANS	105
<i>Climara 100 (BN)</i>	
.GENITO URINARY SYSTEM AND SEX HORMONES .	207
<i>Climara 25 (BN)</i>	
.GENITO URINARY SYSTEM AND SEX HORMONES .	207
<i>Climara 50 (BN)</i>	
.GENITO URINARY SYSTEM AND SEX HORMONES .	207
<i>Climara 75 (BN)</i>	
.GENITO URINARY SYSTEM AND SEX HORMONES .	207
CLINDAMYCIN	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	240
<i>Clindamycin-Link (LM)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	240
<i>Clobemix (GN)</i>	
.NERVOUS SYSTEM.....	569, 570
CLOBETASOL	
.DERMATOLOGICALS.....	197
<i>Clobex (GA)</i>	
.DERMATOLOGICALS.....	197
CLODRONATE	
.MUSCULO-SKELETAL SYSTEM	498
<i>Clofen 10 (AF)</i>	
.MUSCULO-SKELETAL SYSTEM	496
<i>Clofen 25 (AF)</i>	
.MUSCULO-SKELETAL SYSTEM	496
<i>Clomid (SW)</i>	
.GENITO URINARY SYSTEM AND SEX HORMONES .	210
CLOMIPHENE	
.GENITO URINARY SYSTEM AND SEX HORMONES .	210
CLOMIPRAMINE	
.NERVOUS SYSTEM.....	563
<i>Clonac 25 (QA)</i>	
.MUSCULO-SKELETAL SYSTEM	490
.Palliative Care	667
<i>Clonac 50 (QA)</i>	
.MUSCULO-SKELETAL SYSTEM	490
.Palliative Care.....	667, 668
CLONAZEPAM	
.NERVOUS SYSTEM.....	528
.Palliative Care.....	674
<i>Clonea (AF)</i>	
.Repatriation Schedule	1250
CLONIDINE	
.CARDIOVASCULAR SYSTEM	125
CLOPIDOGREL	
.BLOOD AND BLOOD FORMING ORGANS.....	106, 107
.Repatriation Schedule	1248
CLOPIDOGREL + ASPIRIN	
.BLOOD AND BLOOD FORMING ORGANS.....	108
<i>Clopidogrel Actavis (UA)</i>	
.BLOOD AND BLOOD FORMING ORGANS.....	108
<i>Clopidogrel AN (EA)</i>	
.BLOOD AND BLOOD FORMING ORGANS.....	106, 107
<i>Clopidogrel GH (GQ)</i>	
.BLOOD AND BLOOD FORMING ORGANS.....	108
.Repatriation Schedule	1248
<i>Clopidogrel RBX (RA)</i>	
.BLOOD AND BLOOD FORMING ORGANS.....	107
<i>Clopidogrel Sandoz (SZ)</i>	
.BLOOD AND BLOOD FORMING ORGANS.....	107
<i>Clopidogrel Winthrop (WA)</i>	
.BLOOD AND BLOOD FORMING ORGANS.....	106, 107
<i>Clopidogrel Winthrop plus aspirin (WA)</i>	
.BLOOD AND BLOOD FORMING ORGANS.....	108
<i>Clopidogrel/Aspirin Actavis 75/100 (GN)</i>	
.BLOOD AND BLOOD FORMING ORGANS.....	108
<i>Clopidogrel-DRLA (RZ)</i>	
.BLOOD AND BLOOD FORMING ORGANS.....	107
<i>Clopidogrel-GA (GN)</i>	
.BLOOD AND BLOOD FORMING ORGANS.....	106, 108
<i>Clopine 100 (HH)</i>	
.Section 100.....	920, 1178
<i>Clopine 200 (HH)</i>	
.Section 100.....	920, 1178
<i>Clopine 25 (HH)</i>	
.Section 100.....	920, 1178
<i>Clopine 50 (HH)</i>	
.Section 100.....	920, 1178
<i>Clopine Suspension (HH)</i>	
.Section 100.....	920, 1179
<i>Clopixol Depot (LU)</i>	
.NERVOUS SYSTEM.....	545
CLOSTRIDIUM BOTULINUM TYPE A TOXIN- HAEMAGGLUTININ COMPLEX	
.Section 100.....	1201
CLOTRIMAZOLE	
.Repatriation Schedule	1250, 1256
<i>Clovix 75 (QA)</i>	
.BLOOD AND BLOOD FORMING ORGANS.....	106, 108
CLOZAPINE	
.Section 100.....	920, 1178

GENERIC/PROPRIETARY INDEX

<i>Clozaril 100 (NV)</i>		
.Section 100	920, 1178	
<i>Clozaril 25 (NV)</i>		
.Section 100	920, 1178	
COAL TAR PREPARED		
.DERMATOLOGICALS	193	
COAL TAR SOLUTION + PHENOL + SULFUR-PRECIPIATED		
.Repatriation Schedule	1252	
COAL TAR SOLUTION + TAR + SALICYLIC ACID		
.Repatriation Schedule	1253	
<i>Coban 1584 (MM)</i>		
.Repatriation Schedule	1274	
<i>Coban 2 (MM)</i>		
.Repatriation Schedule	1274	
<i>Cobasol (GN)</i>		
.NERVOUS SYSTEM	541	
<i>Codalgin (FM)</i>		
.Repatriation Schedule	1263	
<i>Codalgin Forte (FM)</i>		
.NERVOUS SYSTEM	516, 517	
<i>Codapane Forte (AL)</i>		
.NERVOUS SYSTEM	516, 517	
CODEINE		
.NERVOUS SYSTEM	511	
.RESPIRATORY SYSTEM	604	
<i>Co-Diovan 160/12.5 (NV)</i>		
.CARDIOVASCULAR SYSTEM	151	
<i>Co-Diovan 160/25 (NV)</i>		
.CARDIOVASCULAR SYSTEM	151	
<i>Co-Diovan 320/12.5 (NV)</i>		
.CARDIOVASCULAR SYSTEM	151	
<i>Co-Diovan 320/25 (NV)</i>		
.CARDIOVASCULAR SYSTEM	152	
<i>Co-Diovan 80/12.5 (NV)</i>		
.CARDIOVASCULAR SYSTEM	151	
<i>Cogentin (FK)</i>		
.NERVOUS SYSTEM	539	
.Prescriber Bag	56	
<i>Colazide (PK)</i>		
.ALIMENTARY TRACT AND METABOLISM	78	
COLCHICINE		
.MUSCULO-SKELETAL SYSTEM	497	
<i>Colese (AF)</i>		
.Repatriation Schedule	1244	
<i>Colestid (PF)</i>		
.CARDIOVASCULAR SYSTEM	170	
COLESTIPOL HYDROCHLORIDE		
.CARDIOVASCULAR SYSTEM	170	
<i>Colgout (AS)</i>		
.MUSCULO-SKELETAL SYSTEM	497	
<i>Colifoam (HM)</i>		
.ALIMENTARY TRACT AND METABOLISM	77	
<i>Colofac (GO)</i>		
.Repatriation Schedule	1244	
<i>Coloxyl 50 (FM)</i>		
.Repatriation Schedule	1244	
<i>Coloxyl with Senna (FM)</i>		
.Repatriation Schedule	1245	
<i>CombiDERM 651027 (CC)</i>		
.Repatriation Schedule	1281	
<i>CombiDERM 651031 (CC)</i>		
.Repatriation Schedule	1281	
<i>Combigan (AG)</i>		
.SENSORY ORGANS	608, 609	
<i>Combivir (VI)</i>		
.Section 100	753, 1010	
<i>Comfarol Forte (SZ)</i>		
.NERVOUS SYSTEM	516, 517	
<i>Comfeel Paste 4701 (CT)</i>		
.Repatriation Schedule	1282	
<i>Comfeel Plus Pressure Relieving 3350 (CT)</i>		
.Repatriation Schedule	1283	
<i>Comfeel Plus Pressure Relieving 3353 (CT)</i>		
.Repatriation Schedule	1283	
<i>Comfeel Plus Transparent 3530 (CT)</i>		
.Repatriation Schedule	1282	
<i>Comfeel Plus Transparent 3533 (CT)</i>		
.Repatriation Schedule	1282	
<i>Comfeel Plus Transparent 3536 (CT)</i>		
.Repatriation Schedule	1282	
<i>Comfeel Plus Ulcer Dressing 3110 (CT)</i>		
.Repatriation Schedule	1283	
<i>Comfeel Purilon Gel 3900 (CT)</i>		
.Repatriation Schedule	1284	
<i>Comfeel SeaSorb Dressing 3705 (CT)</i>		
.Repatriation Schedule	1277	
<i>Comfeel SeaSorb Dressing 3710 (CT)</i>		
.Repatriation Schedule	1277	
<i>Comfeel SeaSorb Filler 3740 (CT)</i>		
.Repatriation Schedule	1277	
<i>Comprilan 01027-00 (BV)</i>		
.Repatriation Schedule	1273	
<i>Comtan (NV)</i>		
.NERVOUS SYSTEM	543	
<i>Concerta (JC)</i>		
.NERVOUS SYSTEM	575	
<i>Condyline Paint (NQ)</i>		
.Repatriation Schedule	1252	
<i>Contour (IK)</i>		
.VARIOUS	630, 631	
<i>Contour next (IK)</i>		
.VARIOUS	630, 631	
<i>Copaxone (TB)</i>		
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	304	
<i>Coperin (AF)</i>		
.NERVOUS SYSTEM	570, 571	
<i>CoPlavix (SW)</i>		
.BLOOD AND BLOOD FORMING ORGANS	108	
<i>Coralan (SE)</i>		

GENERIC/PROPRIETARY INDEX

.CARDIOVASCULAR SYSTEM	125	<i>Coversyl Plus LD 2.5mg/0.625mg (SE)</i>	
<i>Corbeton 40 (AF)</i>		.CARDIOVASCULAR SYSTEM	141
.CARDIOVASCULAR SYSTEM	128	<i>Cozavan (AF)</i>	
<i>Cordarone X 100 (SW)</i>		.CARDIOVASCULAR SYSTEM	146
.CARDIOVASCULAR SYSTEM	122	<i>Creon 10,000 (GO)</i>	
<i>Cordarone X 200 (SW)</i>		.ALIMENTARY TRACT AND METABOLISM	80, 81
.CARDIOVASCULAR SYSTEM	122	<i>Creon 25,000 (GO)</i>	
<i>Cordilox 180 SR (GT)</i>		.ALIMENTARY TRACT AND METABOLISM	80, 81
.CARDIOVASCULAR SYSTEM	133	<i>Creon 40,000 (GO)</i>	
<i>Cordilox SR (GT)</i>		.ALIMENTARY TRACT AND METABOLISM	80, 81
.CARDIOVASCULAR SYSTEM	134	<i>Creon Micro (GO)</i>	
CORIFOLLITROPIN ALFA		.ALIMENTARY TRACT AND METABOLISM	81
.Section 100	1205	<i>Crestor (AP)</i>	
<i>Cortate (AS)</i>		.CARDIOVASCULAR SYSTEM .. 161, 162, 163, 164, 165,	
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX		166	
HORMONES AND INSULINS	216	<i>Crinone 8% (SG)</i>	
<i>Cortic-DS 1% (FM)</i>		.Section 100	1207
.DERMATOLOGICALS	195	<i>Crixivan 400 mg (MK)</i>	
CORTISONE		.Section 100	741, 997
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX		CROMOGLYCATE	
HORMONES AND INSULINS	216	.Repatriation Schedule	1267
<i>Cortival 1/2 (FM)</i>		.RESPIRATORY SYSTEM	602
.DERMATOLOGICALS	196	.SENSORY ORGANS	614
<i>Cortival 1/5 (FM)</i>		<i>Crosuva 10 (ZP)</i>	
.DERMATOLOGICALS	196	.CARDIOVASCULAR SYSTEM	162, 163, 165
<i>Cosamide (AF)</i>		<i>Crosuva 20 (ZP)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING		.CARDIOVASCULAR SYSTEM	162, 163, 164, 165
AGENTS	295	<i>Crosuva 40 (ZP)</i>	
<i>Cosdor (QA)</i>		.CARDIOVASCULAR SYSTEM	162, 163, 164, 165
.SENSORY ORGANS	610	<i>Crosuva 5 (ZP)</i>	
<i>Co-Senna (PP)</i>		.CARDIOVASCULAR SYSTEM	162, 163, 164, 166
.Repatriation Schedule	1245	<i>Crysanal (MD)</i>	
<i>Cosopt (MK)</i>		.MUSCULO-SKELETAL SYSTEM	494
.SENSORY ORGANS	610	.Palliative Care	670
<i>Cosudex (AP)</i>		<i>Curam (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING		.ANTIINFECTIVES FOR SYSTEMIC USE	229
AGENTS	295	<i>Curam Duo (SZ)</i>	
<i>Coumadin (QA)</i>		.ANTIINFECTIVES FOR SYSTEMIC USE	229
.BLOOD AND BLOOD FORMING ORGANS	104	<i>Curam Duo 500/125 (SZ)</i>	
<i>Coveram 10/10 (SE)</i>		.ANTIINFECTIVES FOR SYSTEMIC USE	229, 230
.CARDIOVASCULAR SYSTEM	143	<i>Curam Duo Forte 875/125 (SZ)</i>	
<i>Coveram 10/5 (SE)</i>		.ANTIINFECTIVES FOR SYSTEMIC USE	230
.CARDIOVASCULAR SYSTEM	143	<i>Curity 4112 (KE)</i>	
<i>Coveram 5/10 (SE)</i>		.Repatriation Schedule	1280
.CARDIOVASCULAR SYSTEM	143	<i>Cutifilm Plus 36361370 (SN)</i>	
<i>Coveram 5/5 (SE)</i>		.Repatriation Schedule	1278
.CARDIOVASCULAR SYSTEM	143	<i>Cutifilm Plus 36361371 (SN)</i>	
<i>Coversyl 10mg (SE)</i>		.Repatriation Schedule	1278
.CARDIOVASCULAR SYSTEM	137	<i>Cutilin Non-Stick Wound Pad 36361374 (SN)</i>	
<i>Coversyl 2.5mg (SE)</i>		.Repatriation Schedule	1285
.CARDIOVASCULAR SYSTEM	137	<i>Cutilin Non-Stick Wound Pad 36361375 (SN)</i>	
<i>Coversyl 5mg (SE)</i>		.Repatriation Schedule	1285
.CARDIOVASCULAR SYSTEM	137	<i>Cutinova Hydro 66047441 (SN)</i>	
<i>Coversyl Plus 5mg/1.25mg (SE)</i>		.Repatriation Schedule	1282
.CARDIOVASCULAR SYSTEM	141	<i>Cutinova Hydro 66047443 (SN)</i>	

GENERIC/PROPRIETARY INDEX

.Repatriation Schedule	1282
CYANOCOBALAMIN + FERRIC PYROPHOSPHATE + LYSINE + PYRIDOXINE + THIAMINE	
.Repatriation Schedule	1246
<i>Cycloblastin (ZX)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	256
CYCLOPHOSPHAMIDE	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	256
CYCLOSPORIN	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	488
.Section 100	903, 1161, 1162
<i>Cyclosporin Sandoz (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	488
.Section 100	903, 1161
<i>Cyklokapron (PF)</i>	
.BLOOD AND BLOOD FORMING ORGANS	118
<i>Cymbalta (LY)</i>	
.NERVOUS SYSTEM	570, 571
<i>Cymevene (RO)</i>	
.Section 100	737, 993
<i>Cyprocur 100 (QA)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	295
.GENITO URINARY SYSTEM AND SEX HORMONES .	210
<i>Cyprocur 50 (QA)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	295
.GENITO URINARY SYSTEM AND SEX HORMONES .	211
CYPROHEPTADINE	
.NERVOUS SYSTEM	527
<i>Cyprone (AF)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	295
.GENITO URINARY SYSTEM AND SEX HORMONES .	211
<i>Cyprostat (SY)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	295
.GENITO URINARY SYSTEM AND SEX HORMONES .	211
<i>Cyprostat-100 (SY)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	295
.GENITO URINARY SYSTEM AND SEX HORMONES .	210
CYPROTERONE	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	295
.GENITO URINARY SYSTEM AND SEX HORMONES 210, 211	
<i>Cyproterone AN (EA)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	295

.GENITO URINARY SYSTEM AND SEX HORMONES 210, 211	
<i>Cyproterone Sandoz (HX)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	295
.GENITO URINARY SYSTEM AND SEX HORMONES 210, 211	
<i>Cyrotone (ER)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	295
.GENITO URINARY SYSTEM AND SEX HORMONES .	211
<i>Cystadane (EU)</i>	
.ALIMENTARY TRACT AND METABOLISM	102
<i>Cystine 500 (VF)</i>	
.VARIOUS	656
CYSTINE WITH CARBOHYDRATE	
.VARIOUS	656

D

DABIGATRAN	
.BLOOD AND BLOOD FORMING ORGANS	110, 111
DABRAFENIB	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	259, 260
<i>Daivobet (LO)</i>	
.DERMATOLOGICALS	194
<i>Daivobet 50/500 gel (LO)</i>	
.DERMATOLOGICALS	194
<i>Daivonex (LO)</i>	
.DERMATOLOGICALS	193
<i>Daktarin (JT)</i>	
.DERMATOLOGICALS	192
.Repatriation Schedule	1250
<i>Daktarin Tincture (JT)</i>	
.DERMATOLOGICALS	192
.Repatriation Schedule	1250
<i>Dalacin C (PF)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE	240
DALTEPARIN SODIUM	
.BLOOD AND BLOOD FORMING ORGANS	104, 105
DANAZOL	
.GENITO URINARY SYSTEM AND SEX HORMONES .	211
<i>Dantrium (PF)</i>	
.MUSCULO-SKELETAL SYSTEM	496
DANTROLENE	
.MUSCULO-SKELETAL SYSTEM	496
<i>Daonil (SW)</i>	
.ALIMENTARY TRACT AND METABOLISM	84
DAPAGLIFLOZIN	
.ALIMENTARY TRACT AND METABOLISM	97
<i>Dapa-Tabs (AF)</i>	
.CARDIOVASCULAR SYSTEM	126
DAPSONE	
.ANTIINFECTIVES FOR SYSTEMIC USE	249

GENERIC/PROPRIETARY INDEX

.DERMATOLOGICALS.....	198	.GENITO URINARY SYSTEM AND SEX HORMONES .	202
<i>Daraprim (AS)</i>		<i>Deptran 10 (AF)</i>	
.ANTIPARASITIC PRODUCTS, INSECTICIDES AND		.NERVOUS SYSTEM.....	564
REPELLENTS.....	591	<i>Deptran 25 (AF)</i>	
DARBEPOETIN ALFA		.NERVOUS SYSTEM.....	564
.Section 100	684, 939	<i>Deptran 50 (AF)</i>	
<i>Dario (UH)</i>		.NERVOUS SYSTEM.....	564
.VARIOUS.....	630, 631	<i>Deralin 10 (AF)</i>	
DARUNAVIR		.CARDIOVASCULAR SYSTEM	128
.Section 100	740, 996	<i>Deralin 160 (AF)</i>	
DASATINIB		.CARDIOVASCULAR SYSTEM	128
.ANTINEOPLASTIC AND IMMUNOMODULATING		<i>Deralin 40 (AF)</i>	
AGENTS	260, 262, 264	.CARDIOVASCULAR SYSTEM	128
<i>DBL Cefepime (HH)</i>		<i>Dermatane (ER)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	237	.DERMATOLOGICALS.....	197, 198
<i>DBL Gabapentin (HH)</i>		<i>Desfax (AF)</i>	
.Repatriation Schedule.....	1263	.NERVOUS SYSTEM.....	570
<i>DBL Metronidazole Intravenous Infusion (HH)</i>		<i>Desferal 2 g (NV)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	244, 245	.Section 100.....	933, 1196
<i>Deca-Durabolin (AS)</i>		<i>Desferal 500 mg (NV)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	102	.Section 100.....	933, 1196
DEFERASIROX		DESFERRIOXAMINE	
.Section 100	933, 1196	.Section 100.....	933, 1196
DEFERIPRONE		DESMOPRESSIN	
.Section 100	933, 1196	.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX	
DEGARELIX		HORMONES AND INSULINS.....	214, 215
.ANTINEOPLASTIC AND IMMUNOMODULATING		DESVENLAFAXINE	
AGENTS	299	.NERVOUS SYSTEM.....	570
<i>Delucon 100 (DO)</i>		<i>Desvenlafaxine Actavis (GN)</i>	
.NERVOUS SYSTEM.....	552	.NERVOUS SYSTEM.....	570
<i>Delucon 200 (DO)</i>		<i>Desvenlafaxine GH XR (GQ)</i>	
.NERVOUS SYSTEM.....	552	.NERVOUS SYSTEM.....	570
<i>Delucon 25 (DO)</i>		DEXAMETHASONE	
.NERVOUS SYSTEM.....	554	.SENSORY ORGANS.....	607
<i>Delucon 300 (DO)</i>		.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX	
.NERVOUS SYSTEM.....	553	HORMONES AND INSULINS.....	216
DENOSUMAB		DEXAMETHASONE + FRAMYCETIN SULFATE +	
.MUSCULO-SKELETAL SYSTEM	507	GRAMICIDIN	
<i>Denpax (AF)</i>		.SENSORY ORGANS.....	624
.NERVOUS SYSTEM.....	517, 518, 519	DEXAMETHASONE SODIUM PHOSPHATE	
<i>Densate 70 (DO)</i>		.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX	
.MUSCULO-SKELETAL SYSTEM	498	HORMONES AND INSULINS.....	216
<i>Deotine 30 (SZ)</i>		DEXAMPHETAMINE	
.NERVOUS SYSTEM.....	570	.NERVOUS SYSTEM.....	574
<i>Deotine 60 (SZ)</i>		<i>Dexmethsone (AF)</i>	
.NERVOUS SYSTEM.....	571	.Prescriber Bag	56
<i>Depo-Medrol (PF)</i>		.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX	
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX		HORMONES AND INSULINS.....	216
HORMONES AND INSULINS.....	218	<i>Dexmethsone (AS)</i>	
<i>Depo-Nisolone (FZ)</i>		.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX	
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX		HORMONES AND INSULINS.....	216
HORMONES AND INSULINS.....	218	DEXTRAN-70 + HYPROMELLOSE	
<i>Depo-Provera (PF)</i>		.SENSORY ORGANS.....	620, 621
.GENITO URINARY SYSTEM AND SEX HORMONES .	202	<i>Diabex (AL)</i>	
<i>Depo-Ralovera (FZ)</i>		.ALIMENTARY TRACT AND METABOLISM.....	83

GENERIC/PROPRIETARY INDEX

<i>Diabex 1000 (AL)</i>		<i>.Repatriation Schedule</i> 1261
<i>.ALIMENTARY TRACT AND METABOLISM</i>	83	
<i>Diabex 850 (AL)</i>		<i>Diclofenac AN (EA)</i>
<i>.ALIMENTARY TRACT AND METABOLISM</i>	84	<i>.MUSCULO-SKELETAL SYSTEM</i> 490
<i>Diabex XR (AL)</i>		<i>.Palliative Care</i> 667, 668
<i>.ALIMENTARY TRACT AND METABOLISM</i>	84	<i>Diclofenac Sandoz (SZ)</i>
<i>Diabex XR 1000 (AL)</i>		<i>.MUSCULO-SKELETAL SYSTEM</i> 490
<i>.ALIMENTARY TRACT AND METABOLISM</i>	83	<i>.Palliative Care</i> 667, 668
<i>Diaformin (AF)</i>		<i>Diclofenac-GA (GN)</i>
<i>.ALIMENTARY TRACT AND METABOLISM</i>	83	<i>.MUSCULO-SKELETAL SYSTEM</i> 490
<i>Diaformin 1000 (AF)</i>		<i>.Palliative Care</i> 667, 668
<i>.ALIMENTARY TRACT AND METABOLISM</i>	83	DICLOXACILLIN
<i>Diaformin 850 (AF)</i>		<i>.ANTIINFECTIVES FOR SYSTEMIC USE</i> 228
<i>.ALIMENTARY TRACT AND METABOLISM</i>	84	DIDANOSINE
<i>Diaformin XR (AF)</i>		<i>.Section 100</i> 745, 1001
<i>.ALIMENTARY TRACT AND METABOLISM</i>	84	<i>Diffiam (IA)</i>
<i>Diaformin XR 1000 (AF)</i>		<i>.ALIMENTARY TRACT AND METABOLISM</i> 60
<i>.ALIMENTARY TRACT AND METABOLISM</i>	83	<i>.Palliative Care</i> 662
<i>Dialamine (SB)</i>		<i>Diflucan (PF)</i>
<i>.VARIOUS</i>	656	<i>.ANTIINFECTIVES FOR SYSTEMIC USE</i> 246
<i>Diamicron 60mg MR (SE)</i>		<i>Digestelact (SJ)</i>
<i>.ALIMENTARY TRACT AND METABOLISM</i>	84	<i>.VARIOUS</i> 650
<i>Diamox (QA)</i>		DIGOXIN
<i>.SENSORY ORGANS</i>	609	<i>.CARDIOVASCULAR SYSTEM</i> 121
<i>Diapride 1 (QA)</i>		<i>Dilantin (PF)</i>
<i>.ALIMENTARY TRACT AND METABOLISM</i>	84	<i>.NERVOUS SYSTEM</i> 528
<i>Diapride 2 (QA)</i>		<i>Dilantin Infatabs (PF)</i>
<i>.ALIMENTARY TRACT AND METABOLISM</i>	85	<i>.NERVOUS SYSTEM</i> 528
<i>Diapride 3 (QA)</i>		<i>Dilantin Sodium (PF)</i>
<i>.ALIMENTARY TRACT AND METABOLISM</i>	85	<i>.NERVOUS SYSTEM</i> 528
<i>Diapride 4 (QA)</i>		<i>Dilart (AF)</i>
<i>.ALIMENTARY TRACT AND METABOLISM</i>	85	<i>.CARDIOVASCULAR SYSTEM</i> 147
<i>Diastix (BN)</i>		<i>Dilart HCT 160/12.5 (AF)</i>
<i>.VARIOUS</i>	629	<i>.CARDIOVASCULAR SYSTEM</i> 151
DIAZEPAM		<i>Dilart HCT 160/25 (AF)</i>
<i>.NERVOUS SYSTEM</i>	560	<i>.CARDIOVASCULAR SYSTEM</i> 151
<i>.Palliative Care</i>	674	<i>Dilart HCT 320/12.5 (AF)</i>
<i>Diazepam Elixir (ON)</i>		<i>.CARDIOVASCULAR SYSTEM</i> 151
<i>.NERVOUS SYSTEM</i>	560	<i>Dilart HCT 320/25 (AF)</i>
<i>Dibenyline (GH)</i>		<i>.CARDIOVASCULAR SYSTEM</i> 152
<i>.CARDIOVASCULAR SYSTEM</i>	128	<i>Dilart HCT 80/12.5 (AF)</i>
<i>.GENITO URINARY SYSTEM AND SEX HORMONES</i> .	212	<i>.CARDIOVASCULAR SYSTEM</i> 151
<i>Dibenzylone (BZ)</i>		<i>Dilatrend 12.5 (RO)</i>
<i>.CARDIOVASCULAR SYSTEM</i>	128	<i>.CARDIOVASCULAR SYSTEM</i> 131
<i>.GENITO URINARY SYSTEM AND SEX HORMONES</i> .	212	<i>Dilatrend 25 (RO)</i>
<i>Dicarz (AF)</i>		<i>.CARDIOVASCULAR SYSTEM</i> 131
<i>.CARDIOVASCULAR SYSTEM</i>	131, 132	<i>Dilatrend 3.125 (RO)</i>
DICHLOROBENZENE WITH CHLORIBUTOL AND ARACHIS OIL		<i>.CARDIOVASCULAR SYSTEM</i> 131
<i>.Repatriation Schedule</i>	1269	<i>Dilatrend 6.25 (RO)</i>
DICLOFENAC		<i>.CARDIOVASCULAR SYSTEM</i> 132
<i>.MUSCULO-SKELETAL SYSTEM</i>	490	<i>Dilaudid (MF)</i>
<i>.Palliative Care</i>	667	<i>.NERVOUS SYSTEM</i> 511, 512
<i>.Repatriation Schedule</i>	1254	<i>Dilaudid-HP (MF)</i>
DICLOFENAC + MISOPROSTOL		<i>.NERVOUS SYSTEM</i> 511, 512
		DILTIAZEM
		<i>.CARDIOVASCULAR SYSTEM</i> 134

GENERIC/PROPRIETARY INDEX

<i>Diltiazem Actavis (UA)</i>		
.CARDIOVASCULAR SYSTEM	134	
<i>Diltiazem AN (EA)</i>		
.CARDIOVASCULAR SYSTEM	134	
<i>Diltiazem Sandoz (SZ)</i>		
.CARDIOVASCULAR SYSTEM	134	
<i>Diltiazem Sandoz CD (SZ)</i>		
.CARDIOVASCULAR SYSTEM	134	
<i>Dilzem 60 mg (GN)</i>		
.CARDIOVASCULAR SYSTEM	134	
DIMETHICONE-350 + GLYCEROL		
.Repatriation Schedule	1251	
DIMETHYL FUMARATE		
.NERVOUS SYSTEM	588, 589	
<i>Dimetriose (SW)</i>		
.GENITO URINARY SYSTEM AND SEX HORMONES .	211	
<i>Dimirel (AV)</i>		
.ALIMENTARY TRACT AND METABOLISM	84, 85	
<i>Diovan (NV)</i>		
.CARDIOVASCULAR SYSTEM	147	
<i>Dipentum (IX)</i>		
.ALIMENTARY TRACT AND METABOLISM	80	
DIPHENOXYLATE + ATROPINE SULFATE		
.ALIMENTARY TRACT AND METABOLISM	77	
<i>Diphereline (IS)</i>		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	294	
DIPHThERIA TOXOID + TETANUS TOXOID		
.ANTIINFECTIVES FOR SYSTEMIC USE	255	
<i>Diprosone (MK)</i>		
.DERMATOLOGICALS	196	
DIPYRIDAMOLE		
.BLOOD AND BLOOD FORMING ORGANS	108	
DIPYRIDAMOLE + ASPIRIN		
.BLOOD AND BLOOD FORMING ORGANS	109	
DISOPYRAMIDE		
.CARDIOVASCULAR SYSTEM	121	
<i>Distaph 250 (AF)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE	228	
<i>Distaph 500 (AF)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE	228	
<i>Dithiazide (PL)</i>		
.CARDIOVASCULAR SYSTEM	126	
<i>Ditropan (SW)</i>		
.GENITO URINARY SYSTEM AND SEX HORMONES .	212	
<i>Dizole 100 (AF)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE	246	
<i>Dizole 200 (AF)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE	246	
<i>Dizole 50 (AF)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE	246	
<i>docomega (VF)</i>		
.VARIOUS	656	
DOCOSAHEXAENOIC ACID WITH CARBOHYDRATE		
.VARIOUS	656	
DOCUSATE		
.Repatriation Schedule	1244, 1269	
DOCUSATE + SENNOSIDE B		
.Repatriation Schedule	1244	
DOCUSATE + SENNOSIDES		
.Repatriation Schedule	1245	
<i>Dolapril 0.5 (QA)</i>		
.CARDIOVASCULAR SYSTEM	140	
<i>Dolapril 1 (QA)</i>		
.CARDIOVASCULAR SYSTEM	140	
<i>Dolapril 2 (QA)</i>		
.CARDIOVASCULAR SYSTEM	140	
<i>Dolapril 4 (QA)</i>		
.CARDIOVASCULAR SYSTEM	140	
DOLUTEGRAVIR		
.Section 100	754, 1011	
DOLUTEGRAVIR + ABACAVIR + LAMIVUDINE		
.Section 100	752, 1009	
DOMPERIDONE		
.ALIMENTARY TRACT AND METABOLISM	67	
DONEPEZIL		
.NERVOUS SYSTEM	576, 577	
<i>Donepezil AN (EA)</i>		
.NERVOUS SYSTEM	576, 577, 578	
<i>Donepezil generichealth (GQ)</i>		
.NERVOUS SYSTEM	576, 577, 578	
<i>Donepezil RBX (RA)</i>		
.NERVOUS SYSTEM	576, 577, 578	
<i>Donepezil Sandoz (SZ)</i>		
.NERVOUS SYSTEM	576, 577, 578	
<i>Donepezil-DRLA (RZ)</i>		
.NERVOUS SYSTEM	576, 577, 578	
<i>Donepezil-GA (GN)</i>		
.NERVOUS SYSTEM	576, 577, 578	
DORNASE ALFA		
.Section 100	926, 1189	
<i>Doryx (YN)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE	223, 224	
DORZOLAMIDE		
.SENSORY ORGANS	610	
DORZOLAMIDE + TIMOLOL		
.SENSORY ORGANS	610	
<i>Dorzolamide/Timolol Sandoz 20/5 (SZ)</i>		
.SENSORY ORGANS	610	
<i>Dostan (GN)</i>		
.GENITO URINARY SYSTEM AND SEX HORMONES .	201	
<i>Dostinex (PF)</i>		
.GENITO URINARY SYSTEM AND SEX HORMONES .	201	
<i>Dothep 25 (AF)</i>		
.NERVOUS SYSTEM	563	
<i>Dothep 75 (AF)</i>		
.NERVOUS SYSTEM	563	
DOTHIEPIN		
.NERVOUS SYSTEM	563	
DOXEPIIN		

GENERIC/PROPRIETARY INDEX

.NERVOUS SYSTEM.....	563	DRESSING GAUZE PARAFFIN WITH CHLORHEXIDINE ACETATE	
DOXORUBICIN HYDROCHLORIDE-PEGYLATED LIPOSOMAL		.Repatriation Schedule	1280
.Section 100	758, 1015	DRESSING HYDROACTIVE CAVITY WOUND	
<i>Doxsig (QA)</i>		.Repatriation Schedule	1280
.ANTIINFECTIVES FOR SYSTEMIC USE.....	223, 224	DRESSING HYDROACTIVE DEBRIDEMENT	
<i>Doxy-100 (GN)</i>		.Repatriation Schedule	1281
.ANTIINFECTIVES FOR SYSTEMIC USE.....	223, 224	DRESSING HYDROACTIVE SUPERFICIAL WOUND HIGH EXUDATE SEMI-PERMEABLE ABSORBENT FOAM	
<i>Doxy-50 (GN)</i>		.Repatriation Schedule	1281
.ANTIINFECTIVES FOR SYSTEMIC USE.....	224	DRESSING HYDROACTIVE SUPERFICIAL WOUND LIGHT EXUDATE	
DOXYCYCLINE		.Repatriation Schedule	1281
.ANTIINFECTIVES FOR SYSTEMIC USE.....	223, 224	DRESSING HYDROACTIVE SUPERFICIAL WOUND MODERATE EXUDATE	
<i>Doxycycline AN (EA)</i>		.Repatriation Schedule	1281
.ANTIINFECTIVES FOR SYSTEMIC USE.....	223, 224	DRESSING HYDROCOLLOID CAVITY WOUND	
<i>Doxycycline Sandoz (HX)</i>		.Repatriation Schedule	1282
.ANTIINFECTIVES FOR SYSTEMIC USE.....	223, 224	DRESSING HYDROCOLLOID SUPERFICIAL WOUND LIGHT EXUDATE	
<i>Doxylin 100 (AF)</i>		.Repatriation Schedule	1282
.ANTIINFECTIVES FOR SYSTEMIC USE.....	223, 224	DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE	
<i>Doxylin 50 (AF)</i>		.Repatriation Schedule	1282, 1283
.ANTIINFECTIVES FOR SYSTEMIC USE.....	224	DRESSING HYDROFIBRE ALTERNATE TO ALGINATES	
<i>D-Penamine (AL)</i>		.Repatriation Schedule	1283
.MUSCULO-SKELETAL SYSTEM	496	DRESSING HYDROFIBRE GELLING FIBRE	
DRESSING ACTIVATED CHARCOAL MALODOROUS WOUND		.Repatriation Schedule	1283
.Repatriation Schedule	1276	DRESSING HYDROFIBRE WITH SILVER	
DRESSING ALGINATE CAVITY WOUND		.Repatriation Schedule	1284
.Repatriation Schedule	1277	DRESSING HYDROGEL	
DRESSING ALGINATE SUPERFICIAL WOUND		.Repatriation Schedule	1284
.Repatriation Schedule	1277	DRESSING HYDROGEL AMORPHOUS	
DRESSING FILM		.Repatriation Schedule	1284
.Repatriation Schedule	1277, 1278	DRESSING HYDROGEL FOAM	
DRESSING FILM ISLAND		.Repatriation Schedule	1284
.Repatriation Schedule	1278	DRESSING HYDROGEL RIBBON	
DRESSING FOAM HEAVY EXUDATE		.Repatriation Schedule	1284
.Repatriation Schedule	1278	DRESSING HYDROGEL SHEET	
DRESSING FOAM MODERATE EXUDATE		.Repatriation Schedule	1285
.Repatriation Schedule	1278	DRESSING NON ADHERENT	
DRESSING FOAM WITH SILICONE		.Repatriation Schedule	1285
.Repatriation Schedule	1278	DRESSING TULLE NON GAUZE PARAFFIN	
DRESSING FOAM WITH SILICONE AND SILVER		.Repatriation Schedule	1285
.Repatriation Schedule	1279	DRESSING WITH SILVER	
DRESSING FOAM WITH SILICONE HEAVY EXUDATE		.Repatriation Schedule	1286
.Repatriation Schedule	1279	<i>Drixine (BN)</i>	
DRESSING FOAM WITH SILICONE LIGHT EXUDATE		.Repatriation Schedule	1267
.Repatriation Schedule	1279	<i>Dronalen Plus (GN)</i>	
DRESSING FOAM WITH SILICONE MODERATE EXUDATE		.MUSCULO-SKELETAL SYSTEM	502
.Repatriation Schedule	1279	<i>Dronalen Plus D-Cal (FR)</i>	
DRESSING FOAM WITH SILVER		.MUSCULO-SKELETAL SYSTEM	504
.Repatriation Schedule	1280	<i>Drulox (GN)</i>	
DRESSING GAUZE ABSORBENT		.NERVOUS SYSTEM	570, 571
.Repatriation Schedule	1280	<i>Dulcolax (BY)</i>	
DRESSING GAUZE EYE			
.Repatriation Schedule	1280		
DRESSING GAUZE PARAFFIN			
.Repatriation Schedule	1280		

GENERIC/PROPRIETARY INDEX

.ALIMENTARY TRACT AND METABOLISM.....	73	<i>Durogesic 12 (JC)</i>	
.Palliative Care	662, 663	.NERVOUS SYSTEM.....	518
<i>Dulose (FM)</i>		<i>Durogesic 25 (JC)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	73	.NERVOUS SYSTEM.....	518
.Palliative Care	663	<i>Durogesic 50 (JC)</i>	
DULOXETINE		.NERVOUS SYSTEM.....	519
.NERVOUS SYSTEM.....	570	<i>Durogesic 75 (JC)</i>	
<i>Duloxetine AN (EA)</i>		.NERVOUS SYSTEM.....	519
.NERVOUS SYSTEM.....	570, 571	<i>Duro-K (NM)</i>	
<i>Duloxetine GH (GQ)</i>		.ALIMENTARY TRACT AND METABOLISM.....	101
.NERVOUS SYSTEM.....	570, 571	<i>Duro-Tuss (IA)</i>	
<i>Duloxetine RBX (RA)</i>		.Repatriation Schedule	1268
.NERVOUS SYSTEM.....	570, 571	DUTASTERIDE	
<i>Duloxetine-DRLA (RZ)</i>		.GENITO URINARY SYSTEM AND SEX HORMONES .	213
.NERVOUS SYSTEM.....	570, 571	.Repatriation Schedule	1258
<i>Duocal (SB)</i>		DUTASTERIDE + TAMSULOSIN	
.VARIOUS.....	659	.GENITO URINARY SYSTEM AND SEX HORMONES .	213
<i>DuoCover (AV)</i>		.Repatriation Schedule	1257
.BLOOD AND BLOOD FORMING ORGANS	108	<i>Dutran 100 (GN)</i>	
<i>Duodart 500ug/400ug (GK)</i>		.NERVOUS SYSTEM.....	517
.GENITO URINARY SYSTEM AND SEX HORMONES .	213	<i>Dutran 12 (GN)</i>	
.Repatriation Schedule	1257	.NERVOUS SYSTEM.....	518
<i>DuoDERM CGF H7660 (CC)</i>		<i>Dutran 25 (GN)</i>	
.Repatriation Schedule.....	1283	.NERVOUS SYSTEM.....	518
<i>DuoDERM CGF H7662 (CC)</i>		<i>Dutran 50 (GN)</i>	
.Repatriation Schedule.....	1283	.NERVOUS SYSTEM.....	519
<i>DuoDERM Extra Thin H7955 (CC)</i>		<i>Dutran 75 (GN)</i>	
.Repatriation Schedule	1282	.NERVOUS SYSTEM.....	519
<i>DuoDERM Gel H7987 (CC)</i>		<i>Dysport (IS)</i>	
.Repatriation Schedule	1284	.Section 100.....	1202
<i>DuoDERM Gel H7990 (CC)</i>			
.Repatriation Schedule	1284		
<i>DuoDERM Paste H7930 (CC)</i>			
.Repatriation Schedule.....	1282		
<i>Duodopa (VE)</i>			
.NERVOUS SYSTEM.....	539		
.Section 100	920, 1178		
<i>Duofilm Solution (GK)</i>			
.Repatriation Schedule	1253		
<i>DuoPlidogrel (GZ)</i>			
.BLOOD AND BLOOD FORMING ORGANS	108		
<i>Duotrav (AQ)</i>			
.SENSORY ORGANS.....	614		
<i>Durafiber 66800560 (SN)</i>			
.Repatriation Schedule.....	1283		
<i>Durafiber 66800561 (SN)</i>			
.Repatriation Schedule.....	1283		
<i>Durafiber 66800563 (SN)</i>			
.Repatriation Schedule	1283		
<i>Duratears (AQ)</i>			
.SENSORY ORGANS.....	622		
<i>Duride (AF)</i>			
.CARDIOVASCULAR SYSTEM	124		
<i>Durogesic 100 (JC)</i>			
.NERVOUS SYSTEM.....	517		

E

<i>E.E.S. 200 (LM)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE	239
<i>E.E.S. 400 Filmtab (LM)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE	239
<i>E.E.S. Granules (LM)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE	239
<i>EAA Supplement (VF)</i>	
.VARIOUS.....	657
<i>Ear Clear for Ear Wax Removal (KY)</i>	
.Repatriation Schedule	1269
<i>Easiphen (SB)</i>	
.VARIOUS.....	653
<i>EasyMate II (WI)</i>	
.VARIOUS.....	629, 630, 631
<i>Ebixa (LU)</i>	
.NERVOUS SYSTEM.....	583
ECULIZUMAB	
.Section 100.....	791, 792, 793, 1049, 1057, 1058
<i>Edecrin (FK)</i>	
.CARDIOVASCULAR SYSTEM	127
<i>Edronax (PF)</i>	
.NERVOUS SYSTEM.....	572

<i>Edurant (JC)</i>	.ANTINEOPLASTIC AND IMMUNOMODULATING
.Section 100	AGENTS 293
<i>EFAVIRENZ</i>	<i>Eligard 6 month (TL)</i>
.Section 100	.ANTINEOPLASTIC AND IMMUNOMODULATING
<i>Efexor-XR (PF)</i>	AGENTS 293
.NERVOUS SYSTEM.....	<i>Eliquis (BQ)</i>
572, 573	.BLOOD AND BLOOD FORMING ORGANS.....
<i>Effient (LY)</i>	112, 113
.BLOOD AND BLOOD FORMING ORGANS	<i>Elocon (MK)</i>
109	.DERMATOLOGICALS.....
<i>EFORMOTEROL</i>	196, 197
.RESPIRATORY SYSTEM	.Repatriation Schedule.....
594	1253
<i>Efudix (IA)</i>	<i>Elonva (MK)</i>
.Repatriation Schedule.....	.Section 100.....
1260	1205
<i>Egoderm Cream (EO)</i>	<i>ELTROMBOPAG</i>
.Repatriation Schedule.....	.Section 100.....
1254	680, 935
<i>Egoderm Ointment (EO)</i>	<i>Emend (MK)</i>
.Repatriation Schedule.....	.ALIMENTARY TRACT AND METABOLISM.....
1254	72
<i>Egopsoryl-TA (EO)</i>	<i>EMPAGLIFLOZIN</i>
.Repatriation Schedule.....	.ALIMENTARY TRACT AND METABOLISM.....
1252	98
<i>Elastoplast 2225 (BE)</i>	<i>EMTRICITABINE</i>
.Repatriation Schedule.....	.Section 100.....
1275	745, 1002
<i>Elastoplast 2226 (BE)</i>	<i>EMTRICITABINE + RILPIVIRINE + TENOFOVIR</i>
.Repatriation Schedule.....	.Section 100.....
1275	752, 1009
<i>Elastoplast 2227 (BE)</i>	<i>Emtriva (GI)</i>
.Repatriation Schedule.....	.Section 100.....
1275	745, 1002
<i>Elaxine SR 150 (ZP)</i>	<i>E-Mycin (AF)</i>
.NERVOUS SYSTEM.....	.ANTIINFECTIVES FOR SYSTEMIC USE.....
572	239
<i>Elaxine SR 37.5 (ZP)</i>	<i>E-Mycin 200 (AF)</i>
.NERVOUS SYSTEM.....	.ANTIINFECTIVES FOR SYSTEMIC USE.....
573	239
<i>Elaxine SR 75 (ZP)</i>	<i>E-Mycin 400 (AF)</i>
.NERVOUS SYSTEM.....	.ANTIINFECTIVES FOR SYSTEMIC USE.....
573	239
<i>Eldepryl (AS)</i>	<i>ENALAPRIL</i>
.NERVOUS SYSTEM.....	.CARDIOVASCULAR SYSTEM
543	135
<i>Eleanor 150/30 ED (EA)</i>	<i>ENALAPRIL + HYDROCHLOROTHIAZIDE</i>
.GENITO URINARY SYSTEM AND SEX HORMONES .	.CARDIOVASCULAR SYSTEM
201	140
<i>EleCare (AB)</i>	<i>Enalapril Actavis (UA)</i>
.VARIOUS.....	.CARDIOVASCULAR SYSTEM
634, 636	135
<i>EleCare LCP (AB)</i>	<i>Enalapril AN (EA)</i>
.VARIOUS.....	.CARDIOVASCULAR SYSTEM
638, 639	135
<i>ELETRIPTAN</i>	<i>Enalapril generichealth (GQ)</i>
.NERVOUS SYSTEM.....	.CARDIOVASCULAR SYSTEM
524	135
<i>Eleuphrat (FR)</i>	<i>Enalapril Sandoz (SZ)</i>
.DERMATOLOGICALS.....	.CARDIOVASCULAR SYSTEM
195, 196	135
<i>Eleva 100 (AF)</i>	<i>Enalapril/HCT Sandoz (SZ)</i>
.NERVOUS SYSTEM.....	.CARDIOVASCULAR SYSTEM
568, 569	141
<i>Eleva 50 (AF)</i>	<i>Enalapril-GA (GN)</i>
.NERVOUS SYSTEM.....	.CARDIOVASCULAR SYSTEM
568, 569	135
<i>Elidel (HM)</i>	<i>Enbrel (PF)</i>
.DERMATOLOGICALS.....	.ANTINEOPLASTIC AND IMMUNOMODULATING
198	AGENTS 415, 421, 424, 428, 430, 435, 438, 445,
<i>Eligard 1 month (TL)</i>	448, 453, 456
.ANTINEOPLASTIC AND IMMUNOMODULATING	.Section 100.....
AGENTS 293	819, 820, 1078
<i>Eligard 3 month (TL)</i>	<i>Endep 10 (AF)</i>
.ANTINEOPLASTIC AND IMMUNOMODULATING	.NERVOUS SYSTEM.....
AGENTS 293	563
<i>Eligard 4 month (TL)</i>	<i>Endep 25 (AF)</i>
	.NERVOUS SYSTEM.....
	563

GENERIC/PROPRIETARY INDEX

<i>Endep 50 (AF)</i>		
.NERVOUS SYSTEM.....	563	
<i>Endometrin (FP)</i>		
.Section 100	1207	
<i>Endone (QA)</i>		
.NERVOUS SYSTEM.....	515	
<i>Endoxan (BX)</i>		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	256	
<i>Energivit (SB)</i>		
.VARIOUS.....	655	
ENFUVIRTIDE		
.Section 100	754, 1012	
<i>Enidin (PE)</i>		
.SENSORY ORGANS.....	608	
<i>Enlax-XR (AF)</i>		
.NERVOUS SYSTEM.....	572, 573	
ENOXAPARIN SODIUM		
.BLOOD AND BLOOD FORMING ORGANS	105	
ENTACAPONE		
.NERVOUS SYSTEM.....	543	
ENTECAVIR		
.Section 100	745, 746, 1002	
ENZALUTAMIDE		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	295	
<i>Epiduo (GA)</i>		
.DERMATOLOGICALS.....	197	
<i>Epilim (SW)</i>		
.NERVOUS SYSTEM.....	530	
<i>Epilim EC (SW)</i>		
.NERVOUS SYSTEM.....	531	
<i>Epilim Liquid (SW)</i>		
.NERVOUS SYSTEM.....	531	
<i>Epilim Syrup (SW)</i>		
.NERVOUS SYSTEM.....	531	
<i>EpiPen (AL)</i>		
.CARDIOVASCULAR SYSTEM	123	
.RESPIRATORY SYSTEM	602	
<i>EpiPen Jr. (AL)</i>		
.CARDIOVASCULAR SYSTEM	123	
.RESPIRATORY SYSTEM	602	
<i>Epiramax 100 (QA)</i>		
.NERVOUS SYSTEM.....	537	
<i>Epiramax 200 (QA)</i>		
.NERVOUS SYSTEM.....	537	
<i>Epiramax 25 (QA)</i>		
.NERVOUS SYSTEM.....	538	
<i>Epiramax 50 (QA)</i>		
.NERVOUS SYSTEM.....	538	
EPLERENONE		
.CARDIOVASCULAR SYSTEM	127	
EPOETIN ALFA		
.Section 100	684, 939	
EPOETIN BETA		
.Section 100.....	685, 940	
EPOETIN LAMBDA		
.Section 100.....	685, 940	
EPOPROSTENOL		
.Section 100.....	705, 960	
<i>Eprex 1000 (JC)</i>		
.Section 100.....	684, 939	
<i>Eprex 10000 (JC)</i>		
.Section 100.....	684, 939	
<i>Eprex 20,000 (JC)</i>		
.Section 100.....	684, 940	
<i>Eprex 2000 (JC)</i>		
.Section 100.....	685, 940	
<i>Eprex 3000 (JC)</i>		
.Section 100.....	685, 940	
<i>Eprex 40,000 (JC)</i>		
.Section 100.....	685, 940	
<i>Eprex 4000 (JC)</i>		
.Section 100.....	685, 940	
<i>Eprex 5000 (JC)</i>		
.Section 100.....	685, 940	
<i>Eprex 6000 (JC)</i>		
.Section 100.....	685, 940	
<i>Eprex 8000 (JC)</i>		
.Section 100.....	685, 940	
EPROSARTAN		
.CARDIOVASCULAR SYSTEM	144, 145	
EPROSARTAN + HYDROCHLOROTHIAZIDE		
.CARDIOVASCULAR SYSTEM	148	
EPTIFIBATIDE		
.BLOOD AND BLOOD FORMING ORGANS.....	109	
ERLOTINIB		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	265	
<i>Eryc (YN)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	238	
<i>Erythrocine-I.V. (LM)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	239	
ERYTHROMYCIN		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	238	
ERYTHROMYCIN ETHYLSUCCINATE		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	239	
ERYTHROMYCIN LACTOBIONATE		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	239	
<i>Escicor 10 (RA)</i>		
.NERVOUS SYSTEM.....	565	
<i>Escicor 20 (RA)</i>		
.NERVOUS SYSTEM.....	565	
ESCITALOPRAM		
.NERVOUS SYSTEM.....	565, 566	
<i>Escitalopram AN (EA)</i>		
.NERVOUS SYSTEM.....	565	
<i>Escitalopram GA (GN)</i>		
.NERVOUS SYSTEM.....	565	
<i>Escitalopram generichealth (GQ)</i>		

GENERIC/PROPRIETARY INDEX

.NERVOUS SYSTEM.....	565	ETANERCEPT	
<i>Escitalopram-DRLA (RZ)</i>		.ANTINEOPLASTIC AND IMMUNOMODULATING	
.NERVOUS SYSTEM.....	565	AGENTS	402, 415, 421, 424, 428, 430, 435, 438, 445, 448, 453
<i>Esipram (UA)</i>		.Section 100.....	811, 1070
.NERVOUS SYSTEM.....	565, 566	ETHACRYNIC ACID	
<i>Esitalo (SZ)</i>		.CARDIOVASCULAR SYSTEM	127
.NERVOUS SYSTEM.....	565	ETHINYLOESTRADIOL + LEVONORGESTREL	
<i>Eskazole (AS)</i>		.GENITO URINARY SYSTEM AND SEX HORMONES	201, 202
.ANTIPARASITIC PRODUCTS, INSECTICIDES AND		ETHINYLOESTRADIOL + NORETHISTERONE	
REPELLENTS.....	592	.GENITO URINARY SYSTEM AND SEX HORMONES	.202
ESOMEPRAZOLE		ETHOSUXIMIDE	
.ALIMENTARY TRACT AND METABOLISM.....	61, 62	.NERVOUS SYSTEM.....	528
ESOMEPRAZOLE (&) CLARITHROMYCIN (&)		ETONOGESTREL	
AMOXICILLIN		.GENITO URINARY SYSTEM AND SEX HORMONES	.202
.ALIMENTARY TRACT AND METABOLISM.....	67	ETOPOSIDE	
<i>Esomeprazole Apotex (TX)</i>		.ANTINEOPLASTIC AND IMMUNOMODULATING	
.ALIMENTARY TRACT AND METABOLISM.....	62	AGENTS	259
<i>Esomeprazole GxP (AF)</i>		ETRAVIRINE	
.ALIMENTARY TRACT AND METABOLISM.....	62	.Section 100.....	750, 1006
<i>Esomeprazole RBX (RA)</i>		<i>Eucerin (BE)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	62	.Repatriation Schedule	1251
<i>Essential Amino Acid Mix (SB)</i>		<i>Eutroxsig (FM)</i>	
.VARIOUS.....	656	.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX	
ESSENTIAL AMINO ACIDS FORMULA		HORMONES AND INSULINS	219
.VARIOUS.....	656	<i>Evelyn 150/30 ED (GQ)</i>	
ESSENTIAL AMINO ACIDS FORMULA WITH MINERALS		.GENITO URINARY SYSTEM AND SEX HORMONES	.201
AND VITAMIN C		EVEROLIMUS	
.VARIOUS.....	656	.ANTINEOPLASTIC AND IMMUNOMODULATING	
ESSENTIAL AMINO ACIDS FORMULA WITH VITAMINS		AGENTS	266, 267, 268, 269, 314
AND MINERALS		.Section 100.....	801, 1060
.VARIOUS.....	656	<i>Evifyne (EL)</i>	
<i>Estalis continuous 50/140 (NV)</i>		.MUSCULO-SKELETAL SYSTEM	508
.GENITO URINARY SYSTEM AND SEX HORMONES	.208	<i>Eviplera (GI)</i>	
<i>Estalis continuous 50/250 (NV)</i>		.Section 100.....	752, 1009
.GENITO URINARY SYSTEM AND SEX HORMONES	.208	<i>Evista (LY)</i>	
<i>Estalis sequi 50/140 (NV)</i>		.MUSCULO-SKELETAL SYSTEM	508
.GENITO URINARY SYSTEM AND SEX HORMONES	.208	<i>Exaccord (RA)</i>	
<i>Estalis sequi 50/250 (NV)</i>		.ANTINEOPLASTIC AND IMMUNOMODULATING	
.GENITO URINARY SYSTEM AND SEX HORMONES	.208	AGENTS	297, 298
<i>Estraderm MX 100 (NV)</i>		<i>Exelon (NV)</i>	
.GENITO URINARY SYSTEM AND SEX HORMONES	.207	.NERVOUS SYSTEM.....	580, 581, 582
<i>Estraderm MX 25 (NV)</i>		<i>Exelon Patch 10 (NV)</i>	
.GENITO URINARY SYSTEM AND SEX HORMONES	.207	.NERVOUS SYSTEM.....	581, 582
<i>Estraderm MX 50 (NV)</i>		<i>Exelon Patch 5 (NV)</i>	
.GENITO URINARY SYSTEM AND SEX HORMONES	.207	.NERVOUS SYSTEM.....	581, 582
<i>Estradot 100 (NV)</i>		EXEMESTANE	
.GENITO URINARY SYSTEM AND SEX HORMONES	.207	.ANTINEOPLASTIC AND IMMUNOMODULATING	
<i>Estradot 25 (NV)</i>		AGENTS	297
.GENITO URINARY SYSTEM AND SEX HORMONES	.207	<i>Exemestane AN (EA)</i>	
<i>Estradot 37.5 (NV)</i>		.ANTINEOPLASTIC AND IMMUNOMODULATING	
.GENITO URINARY SYSTEM AND SEX HORMONES	.207	AGENTS	297, 298
<i>Estradot 50 (NV)</i>		<i>Exemestane GH (GQ)</i>	
.GENITO URINARY SYSTEM AND SEX HORMONES	.207		

GENERIC/PROPRIETARY INDEX

.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	297, 298
<i>Exemestane Pfizer (FZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	297, 298
<i>Exemestane Sandoz (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	297, 298
<i>Exemestane-GA (GN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	297, 298
EXENATIDE	
.ALIMENTARY TRACT AND METABOLISM.....	99
<i>Exforge 10/160 (NV)</i>	
.CARDIOVASCULAR SYSTEM	152
<i>Exforge 10/320 (NV)</i>	
.CARDIOVASCULAR SYSTEM	152
<i>Exforge 5/160 (NV)</i>	
.CARDIOVASCULAR SYSTEM	152
<i>Exforge 5/320 (NV)</i>	
.CARDIOVASCULAR SYSTEM	152
<i>Exforge 5/80 (NV)</i>	
.CARDIOVASCULAR SYSTEM	152
<i>Exforge HCT 10/160/12.5 (NV)</i>	
.CARDIOVASCULAR SYSTEM	153
<i>Exforge HCT 10/160/25 (NV)</i>	
.CARDIOVASCULAR SYSTEM	153
<i>Exforge HCT 10/320/25 (NV)</i>	
.CARDIOVASCULAR SYSTEM	153
<i>Exforge HCT 5/160/12.5 (NV)</i>	
.CARDIOVASCULAR SYSTEM	153
<i>Exforge HCT 5/160/25 (NV)</i>	
.CARDIOVASCULAR SYSTEM	153
<i>Exjade (NV)</i>	
.Section 100	933, 1196
<i>Exorex (GN)</i>	
.DERMATOLOGICALS.....	193
<i>Extine 20 (QA)</i>	
.NERVOUS SYSTEM.....	568
<i>Eylea (BN)</i>	
.SENSORY ORGANS.....	616
EZETIMIBE	
.CARDIOVASCULAR SYSTEM	170
EZETIMIBE + SIMVASTATIN	
.CARDIOVASCULAR SYSTEM	178, 181
<i>Ezetrol (MK)</i>	
.CARDIOVASCULAR SYSTEM	172
<i>Ezovir (AF)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	251, 252, 253

F

FAMCICLOVIR	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	251, 252
<i>Famciclovir AN (EA)</i>	

.ANTIINFECTIVES FOR SYSTEMIC USE.....	251, 252, 253
<i>Famciclovir generichealth 250 (GQ)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	252
<i>Famciclovir generichealth 500 (GQ)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	253
<i>Famciclovir Sandoz (SZ)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	251, 252, 253
<i>Famciclovir SCP 250 (CR)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	252
<i>Famciclovir-GA (GN)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	251, 252, 253
<i>Famlo (RA)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	252
FAMOTIDINE	
.ALIMENTARY TRACT AND METABOLISM.....	60
<i>Famotidine AN (EA)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	60, 61
<i>Famotidine Sandoz (SZ)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	60, 61
<i>Famvir (NV)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	251, 252, 253
<i>Fareston (MK)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	294
<i>Fasigyn (PF)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	245
<i>Faverin 100 (QA)</i>	
.NERVOUS SYSTEM.....	567
<i>Faverin 50 (QA)</i>	
.NERVOUS SYSTEM.....	567
<i>Favic 125 (QA)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	251
<i>Favic 250 (QA)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	251, 252
<i>Favic 500 (QA)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	252, 253
<i>Fawns and McAllan Proprietary Limited (FM)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	249
.NERVOUS SYSTEM.....	511, 528
.RESPIRATORY SYSTEM.....	604
<i>Febridol (GN)</i>	
.NERVOUS SYSTEM.....	523, 524
<i>Feldene (PF)</i>	
.MUSCULO-SKELETAL SYSTEM	492, 493
<i>Feldene-D (PF)</i>	
.MUSCULO-SKELETAL SYSTEM	493
<i>Felodil XR 10 (QA)</i>	
.CARDIOVASCULAR SYSTEM	132
<i>Felodil XR 5 (QA)</i>	
.CARDIOVASCULAR SYSTEM	133
FELODIPINE	
.CARDIOVASCULAR SYSTEM	132
<i>Felodur ER 10 mg (TX)</i>	
.CARDIOVASCULAR SYSTEM	132
<i>Felodur ER 2.5 mg (TX)</i>	

GENERIC/PROPRIETARY INDEX

.CARDIOVASCULAR SYSTEM	132	<i>Ferrosig (SI)</i>	
<i>Felodur ER 5 mg (TX)</i>		.BLOOD AND BLOOD FORMING ORGANS.....	118
.CARDIOVASCULAR SYSTEM	133	<i>Ferro-tab (AE)</i>	
<i>Femara 2.5 mg (NV)</i>		.BLOOD AND BLOOD FORMING ORGANS.....	118
.ANTINEOPLASTIC AND IMMUNOMODULATING		FERROUS FUMARATE	
AGENTS	298	.BLOOD AND BLOOD FORMING ORGANS.....	118
<i>Femme-Tab ED 20/100 (AE)</i>		FERROUS FUMARATE + FOLIC ACID	
.GENITO URINARY SYSTEM AND SEX HORMONES .	202	.BLOOD AND BLOOD FORMING ORGANS.....	119
<i>Femme-Tab ED 30/150 (AE)</i>		FERROUS SULFATE	
.GENITO URINARY SYSTEM AND SEX HORMONES .	201	.BLOOD AND BLOOD FORMING ORGANS.....	118
<i>Femolet (AF)</i>		<i>Ferrum H (AS)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING		.BLOOD AND BLOOD FORMING ORGANS.....	118
AGENTS	298	<i>Fexal (SZ)</i>	
<i>Femoston 1/10 (GO)</i>		.Repatriation Schedule	1268
.GENITO URINARY SYSTEM AND SEX HORMONES .	209	FEXOFENADINE	
<i>Femoston 2/10 (GO)</i>		.Repatriation Schedule	1268
.GENITO URINARY SYSTEM AND SEX HORMONES .	209	<i>Fibre Health Natural Granular (PP)</i>	
<i>Femoston-Conti (GO)</i>		.Repatriation Schedule	1245
.GENITO URINARY SYSTEM AND SEX HORMONES .	208	<i>Fibsol 10 (QA)</i>	
<i>Fenac (AF)</i>		.CARDIOVASCULAR SYSTEM	136
.MUSCULO-SKELETAL SYSTEM	490	<i>Fibsol 20 (QA)</i>	
.Palliative Care	667, 668	.CARDIOVASCULAR SYSTEM	136
<i>Fenac 25 (AF)</i>		<i>Fibsol 5 (QA)</i>	
.MUSCULO-SKELETAL SYSTEM	490	.CARDIOVASCULAR SYSTEM	136
.Palliative Care	667, 668	FILGRASTIM	
<i>Fendex ER (AF)</i>		.Section 100.....	759, 1016
.CARDIOVASCULAR SYSTEM	132, 133	<i>Finasta (SZ)</i>	
FENOFIBRATE		.Repatriation Schedule	1258
.CARDIOVASCULAR SYSTEM	168, 169	FINASTERIDE	
<i>Fenpatch 100 (ZP)</i>		.Repatriation Schedule	1258
.NERVOUS SYSTEM.....	517	<i>Finasteride Alphapharm (AF)</i>	
<i>Fenpatch 12 (ZP)</i>		.Repatriation Schedule	1258
.NERVOUS SYSTEM.....	518	<i>Finasteride GH 5 (GQ)</i>	
<i>Fenpatch 25 (ZP)</i>		.Repatriation Schedule	1258
.NERVOUS SYSTEM.....	518	<i>Finasteride RBX (RA)</i>	
<i>Fenpatch 50 (ZP)</i>		.Repatriation Schedule	1258
.NERVOUS SYSTEM.....	519	<i>Finasteride-GA 5 (GN)</i>	
<i>Fenpatch 75 (ZP)</i>		.Repatriation Schedule	1258
.NERVOUS SYSTEM.....	519	FINGOLIMOD	
FENTANYL		.ANTINEOPLASTIC AND IMMUNOMODULATING	
.NERVOUS SYSTEM.....	517, 518, 519	AGENTS	315
.Palliative Care	671, 672	<i>Finnacar (QA)</i>	
<i>Fentanyl Sandoz (SZ)</i>		.Repatriation Schedule	1258
.NERVOUS SYSTEM.....	517, 518, 519	<i>Finpro (RZ)</i>	
<i>Fera (QA)</i>		.Repatriation Schedule	1258
.ANTINEOPLASTIC AND IMMUNOMODULATING		<i>Firazyr (ZI)</i>	
AGENTS	298	.BLOOD AND BLOOD FORMING ORGANS.....	120
<i>ferinject (VL)</i>		<i>Firmagon 120mg (FP)</i>	
.BLOOD AND BLOOD FORMING ORGANS	118	.ANTINEOPLASTIC AND IMMUNOMODULATING	
<i>Ferriprox (TX)</i>		AGENTS	299
.Section 100	933, 1196	<i>Firmagon 80mg (FP)</i>	
<i>Ferro-f-tab (AE)</i>		.ANTINEOPLASTIC AND IMMUNOMODULATING	
.BLOOD AND BLOOD FORMING ORGANS	119	AGENTS	299
<i>Ferro-Liquid (AE)</i>		<i>Flagyl (SW)</i>	
.BLOOD AND BLOOD FORMING ORGANS	118	.ANTIINFECTIVES FOR SYSTEMIC USE.....	244

GENERIC/PROPRIETARY INDEX

<i>Flagyl S (SW)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	244	
<i>Flamazine (SN)</i>		
.DERMATOLOGICALS.....	195	
<i>Flarex (AQ)</i>		
.SENSORY ORGANS.....	607	
FLECAINIDE		
.CARDIOVASCULAR SYSTEM.....	121	
<i>Flecatab (AF)</i>		
.CARDIOVASCULAR SYSTEM.....	121	
<i>Flexidress 650941 (CC)</i>		
.Repatriation Schedule.....	1276	
<i>Flixotide (GK)</i>		
.RESPIRATORY SYSTEM.....	601	
<i>Flixotide Accuhaler (GK)</i>		
.RESPIRATORY SYSTEM.....	601	
<i>Flixotide Junior (GK)</i>		
.RESPIRATORY SYSTEM.....	601	
<i>Flixotide Junior Accuhaler (GK)</i>		
.RESPIRATORY SYSTEM.....	601	
<i>Flolan Kit (GK)</i>		
.Section 100.....	710, 965	
<i>Flomaxtra (LS)</i>		
.Repatriation Schedule.....	1257	
<i>Flopen (AS)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	228, 229	
<i>Florinef (QA)</i>		
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS.....	215	
<i>Fluanxol Concentrated Depot (LU)</i>		
.NERVOUS SYSTEM.....	545	
<i>Fluanxol Depot (LU)</i>		
.NERVOUS SYSTEM.....	545	
<i>Flubiclox (GN)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	228	
<i>Flucil (AS)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	228	
<i>Flucil (LN)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	228, 229	
FLUCLOXACILLIN		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	228	
<i>Flucon (AQ)</i>		
.SENSORY ORGANS.....	607	
FLUCONAZOLE		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	245, 246	
<i>Fluconazole Alphapharm (AF)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	246	
<i>Fluconazole Hexal (HX)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	246	
<i>Fluconazole Sandoz (SZ)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	246	
<i>Fludara (GZ)</i>		
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS.....	258	
FLUDARABINE		
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS.....	258	
FLUDROCORTISONE ACETATE		
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS.....	215	
FLUNITRAZEPAM		
.Repatriation Schedule.....	1264	
FLUOROMETHOLONE		
.SENSORY ORGANS.....	607	
FLUOROMETHOLONE ACETATE		
.SENSORY ORGANS.....	607	
FLUOROURACIL		
.Repatriation Schedule.....	1260	
FLUOXETINE		
.NERVOUS SYSTEM.....	567	
<i>Fluoxetine 20 (CR)</i>		
.NERVOUS SYSTEM.....	567	
<i>Fluoxetine AN (EA)</i>		
.NERVOUS SYSTEM.....	567	
<i>Fluoxetine generichealth (GQ)</i>		
.NERVOUS SYSTEM.....	567	
<i>Fluoxetine RBX (RA)</i>		
.NERVOUS SYSTEM.....	567	
<i>Fluoxetine Sandoz (SZ)</i>		
.NERVOUS SYSTEM.....	567	
<i>Fluoxetine-GA (GN)</i>		
.NERVOUS SYSTEM.....	567	
FLUPENTHIXOL DECANOATE		
.NERVOUS SYSTEM.....	545	
FLUPHENAZINE DECANOATE		
.NERVOUS SYSTEM.....	544	
FLURBIPROFEN		
.SENSORY ORGANS.....	608	
FLUTAMIDE		
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS.....	296	
<i>Flutamin (AF)</i>		
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS.....	296	
FLUTICASONE		
.RESPIRATORY SYSTEM.....	601	
FLUTICASONE + EFORMOTEROL		
.RESPIRATORY SYSTEM.....	597	
FLUTICASONE + SALMETEROL		
.RESPIRATORY SYSTEM.....	597, 598	
FLUTICASONE + VILANTEROL		
.RESPIRATORY SYSTEM.....	598, 599	
<i>flutiform 125/5 (MF)</i>		
.RESPIRATORY SYSTEM.....	597	
<i>flutiform 250/10 (MF)</i>		
.RESPIRATORY SYSTEM.....	597	
<i>flutiform 50/5 (MF)</i>		
.RESPIRATORY SYSTEM.....	597	
FLUVASTATIN		
.CARDIOVASCULAR SYSTEM.....	159	

GENERIC/PROPRIETARY INDEX

FLUVOXAMINE		
.NERVOUS SYSTEM.....	567	
<i>Fluvoxamine GA (GN)</i>		
.NERVOUS SYSTEM.....	567	
<i>Fluzole 200 (QA)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	246	
<i>FML Liquifilm (AG)</i>		
.SENSORY ORGANS.....	607	
FOLIC ACID		
.BLOOD AND BLOOD FORMING ORGANS	119	
FOLINIC ACID		
.VARIOUS.....	627, 628	
FOLLITROPIN ALFA		
.GENITO URINARY SYSTEM AND SEX HORMONES .	209	
.Section 100	1205	
FOLLITROPIN BETA		
.GENITO URINARY SYSTEM AND SEX HORMONES .	209	
.Section 100	1205	
<i>Foltabs 500 (PP)</i>		
.BLOOD AND BLOOD FORMING ORGANS	119	
<i>Fonaf (AL)</i>		
.MUSCULO-SKELETAL SYSTEM	498	
<i>Fonaf Plus (AF)</i>		
.MUSCULO-SKELETAL SYSTEM	502	
<i>FonafPlus (AF)</i>		
.MUSCULO-SKELETAL SYSTEM	503	
FONDAPARINUX		
.BLOOD AND BLOOD FORMING ORGANS	117	
<i>Foradile (NV)</i>		
.RESPIRATORY SYSTEM	594	
<i>Formet 1000 (QA)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	83	
<i>Formet Aspen 500 (AS)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	83	
<i>Formet Aspen 850 (AS)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	84	
<i>Forteo (LY)</i>		
.MUSCULO-SKELETAL SYSTEM	510	
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS.....	221	
<i>Forxiga (AP)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	98	
<i>Fosamax Plus (MK)</i>		
.MUSCULO-SKELETAL SYSTEM	503	
.Repatriation Schedule.....	1261	
<i>Fosamax Plus 70 mg/140 mcg (MK)</i>		
.MUSCULO-SKELETAL SYSTEM	503	
.Repatriation Schedule.....	1261	
<i>Fosamax Plus D-Cal (MK)</i>		
.MUSCULO-SKELETAL SYSTEM	504	
.Repatriation Schedule.....	1262	
FOSAMPRENAVIR		
.Section 100	740, 996	
FOSCARNET		
.Section 100	738, 994	
<i>Foscavir (IX)</i>		
.Section 100.....	738, 994	
<i>Fosetic 20/12.5 (ZP)</i>		
.CARDIOVASCULAR SYSTEM	141	
FOSINOPRIL		
.CARDIOVASCULAR SYSTEM	135	
FOSINOPRIL + HYDROCHLOROTHIAZIDE		
.CARDIOVASCULAR SYSTEM	141	
<i>Fosinopril/HCT Actavis 20/12.5 (UA)</i>		
.CARDIOVASCULAR SYSTEM	141	
<i>Fosipril 10 (QA)</i>		
.CARDIOVASCULAR SYSTEM	135	
<i>Fosipril 20 (QA)</i>		
.CARDIOVASCULAR SYSTEM	136	
<i>Fosrenol (ZI)</i>		
.Section 100.....	933, 1196, 1197	
.VARIOUS.....	626, 627	
<i>Fragmin (PF)</i>		
.BLOOD AND BLOOD FORMING ORGANS.....	104, 105	
<i>Frakas (QA)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	224	
FRAMYCETIN SULFATE		
.SENSORY ORGANS.....	625	
<i>FreeStyle Lite (MS)</i>		
.VARIOUS.....	630, 631	
<i>FreeStyle Optium (MS)</i>		
.VARIOUS.....	630, 631	
<i>FruitiVits (VF)</i>		
.VARIOUS.....	660	
<i>Frusax (ER)</i>		
.CARDIOVASCULAR SYSTEM	126	
FRUSEMIDE		
.CARDIOVASCULAR SYSTEM	126, 127	
<i>Fruzemide Sandoz (SZ)</i>		
.CARDIOVASCULAR SYSTEM	126	
.Prescriber Bag	56	
<i>Fruzemide-Clarix (AE)</i>		
.CARDIOVASCULAR SYSTEM	126	
.Prescriber Bag	56	
<i>Frusid (GN)</i>		
.CARDIOVASCULAR SYSTEM	127	
<i>Frusid (UA)</i>		
.CARDIOVASCULAR SYSTEM	126	
<i>Fucidin (CS)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	244	
<i>Fungilin (QA)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	60	
FUSIDATE		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	244	
<i>Fuzeon (RO)</i>		
.Section 100.....	754, 1012	
<i>Fybogel (RC)</i>		
.Repatriation Schedule.....	1245	
<i>Fycompa (EI)</i>		
.NERVOUS SYSTEM.....	536	

GENERIC/PROPRIETARY INDEX

G

<i>GA express 15 (VF)</i>		<i>.NERVOUS SYSTEM</i> 531
<i>.VARIOUS</i>	651	
<i>GA gel (VF)</i>		<i>.NERVOUS SYSTEM</i> 532
<i>.VARIOUS</i>	651	
<i>GA Tramadol 50mg (GN)</i>		<i>.NERVOUS SYSTEM</i> 531
<i>.NERVOUS SYSTEM</i>	522, 523	
<i>GA Tramadol SR 100mg (GN)</i>		<i>.NERVOUS SYSTEM</i> 531
<i>.NERVOUS SYSTEM</i>	521	
<i>GA Tramadol SR 150mg (GN)</i>		<i>.NERVOUS SYSTEM</i> 531
<i>.NERVOUS SYSTEM</i>	521	
<i>GA Tramadol SR 200mg (GN)</i>		<i>.NERVOUS SYSTEM</i> 531
<i>.NERVOUS SYSTEM</i>	521	
<i>GA1 Anamix infant (SB)</i>		<i>.NERVOUS SYSTEM</i> 531
<i>.VARIOUS</i>	651	
<i>GA-Amclav 125/31.25 (GN)</i>		<i>.NERVOUS SYSTEM</i> 532
<i>.ANTIINFECTIVES FOR SYSTEMIC USE</i>	229	
<i>GA-Amclav 500/125 (GN)</i>		<i>.NERVOUS SYSTEM</i> 532
<i>.ANTIINFECTIVES FOR SYSTEMIC USE</i>	229, 230	
<i>GA-Amclav Forte 400/57 (GN)</i>		<i>.NERVOUS SYSTEM</i> 532
<i>.ANTIINFECTIVES FOR SYSTEMIC USE</i>	229	
<i>GA-Amclav Forte 875/125 (GN)</i>		<i>.NERVOUS SYSTEM</i> 532
<i>.ANTIINFECTIVES FOR SYSTEMIC USE</i>	230	
<i>Gabacor (NJ)</i>		<i>.NERVOUS SYSTEM</i> 531
<i>.NERVOUS SYSTEM</i>	531	
<i>GABAPENTIN</i>		<i>.NERVOUS SYSTEM</i> 531
<i>.NERVOUS SYSTEM</i>	531	
<i>.Repatriation Schedule</i>	1263	
<i>Gabapentin 300 (CR)</i>		<i>.NERVOUS SYSTEM</i> 531
<i>.NERVOUS SYSTEM</i>	531	
<i>.Repatriation Schedule</i>	1263	
<i>Gabapentin 400 (CR)</i>		<i>.NERVOUS SYSTEM</i> 531
<i>.NERVOUS SYSTEM</i>	531	
<i>.Repatriation Schedule</i>	1263	
<i>Gabapentin AN (EA)</i>		<i>.NERVOUS SYSTEM</i> 532
<i>.NERVOUS SYSTEM</i>	532	
<i>Gabapentin Aspen 100 (FM)</i>		<i>.NERVOUS SYSTEM</i> 531
<i>.NERVOUS SYSTEM</i>	531	
<i>.Repatriation Schedule</i>	1263	
<i>Gabapentin Aspen 300 (FM)</i>		<i>.NERVOUS SYSTEM</i> 531
<i>.NERVOUS SYSTEM</i>	531	
<i>.Repatriation Schedule</i>	1263	
<i>Gabapentin Aspen 400 (FM)</i>		<i>.NERVOUS SYSTEM</i> 531
<i>.NERVOUS SYSTEM</i>	531	
<i>.Repatriation Schedule</i>	1263	
<i>Gabapentin Aspen 600 (FM)</i>		<i>.NERVOUS SYSTEM</i> 532
<i>.NERVOUS SYSTEM</i>	532	
<i>.Repatriation Schedule</i>	1264	
<i>Gabapentin Aspen 800 (FM)</i>		<i>.NERVOUS SYSTEM</i> 532
<i>.NERVOUS SYSTEM</i>	532	
<i>.Repatriation Schedule</i>	1264	
<i>Gabapentin Sandoz (SZ)</i>		<i>.NERVOUS SYSTEM</i> 531
<i>.NERVOUS SYSTEM</i>	531	
<i>Gabapentin-GA (UA)</i>		<i>.NERVOUS SYSTEM</i> 531
		<i>.NERVOUS SYSTEM</i> 532
<i>Gabaran (RA)</i>		<i>.NERVOUS SYSTEM</i> 532
<i>.NERVOUS SYSTEM</i>	532	
<i>Gabatine 100 (QA)</i>		<i>.NERVOUS SYSTEM</i> 531
<i>.NERVOUS SYSTEM</i>	531	
<i>.Repatriation Schedule</i>	1263	
<i>Gabatine 300 (QA)</i>		<i>.NERVOUS SYSTEM</i> 531
<i>.NERVOUS SYSTEM</i>	531	
<i>.Repatriation Schedule</i>	1263	
<i>Gabatine 400 (QA)</i>		<i>.NERVOUS SYSTEM</i> 531
<i>.NERVOUS SYSTEM</i>	531	
<i>.Repatriation Schedule</i>	1263	
<i>Gabatine 600 (QA)</i>		<i>.NERVOUS SYSTEM</i> 532
<i>.NERVOUS SYSTEM</i>	532	
<i>.Repatriation Schedule</i>	1264	
<i>Gabatine 800 (QA)</i>		<i>.NERVOUS SYSTEM</i> 532
<i>.NERVOUS SYSTEM</i>	532	
<i>.Repatriation Schedule</i>	1264	
<i>Gabitril (OA)</i>		<i>.NERVOUS SYSTEM</i> 530
<i>.NERVOUS SYSTEM</i>	530	
<i>GALANTAMINE</i>		<i>.NERVOUS SYSTEM</i> 578, 579
<i>.NERVOUS SYSTEM</i>	578, 579	
<i>Galantamine AN SR (EA)</i>		<i>.NERVOUS SYSTEM</i> 579, 580
<i>.NERVOUS SYSTEM</i>	579, 580	
<i>Galantyl (AF)</i>		<i>.NERVOUS SYSTEM</i> 579, 580
<i>.NERVOUS SYSTEM</i>	579, 580	
<i>Galvumet 50/1000 (NV)</i>		<i>.ALIMENTARY TRACT AND METABOLISM</i> 90
<i>.ALIMENTARY TRACT AND METABOLISM</i>	90	
<i>Galvumet 50/500 (NV)</i>		<i>.ALIMENTARY TRACT AND METABOLISM</i> 90
<i>.ALIMENTARY TRACT AND METABOLISM</i>	90	
<i>Galvumet 50/850 (NV)</i>		<i>.ALIMENTARY TRACT AND METABOLISM</i> 90
<i>.ALIMENTARY TRACT AND METABOLISM</i>	90	
<i>Galvus (NV)</i>		<i>.ALIMENTARY TRACT AND METABOLISM</i> 96
<i>.ALIMENTARY TRACT AND METABOLISM</i>	96	
<i>Gamine XR (QA)</i>		<i>.NERVOUS SYSTEM</i> 579, 580
<i>.NERVOUS SYSTEM</i>	579, 580	
<i>GANCICLOVIR</i>		<i>.Section 100</i> 737, 993
<i>.Section 100</i>	737, 993	
<i>Ganfort 0.3/5 (AG)</i>		<i>.SENSORY ORGANS</i> 612
<i>.SENSORY ORGANS</i>	612	
<i>GANfort PF 0.3/5 (AG)</i>		<i>.SENSORY ORGANS</i> 612
<i>.SENSORY ORGANS</i>	612	
<i>GANIRELIX</i>		<i>.Section 100</i> 1206
<i>.Section 100</i>	1206	
<i>Gantin (GN)</i>		<i>.NERVOUS SYSTEM</i> 531, 532
<i>.NERVOUS SYSTEM</i>	531, 532	
<i>.Repatriation Schedule</i>	1263, 1264	
<i>Gastrex (CR)</i>		<i>.ALIMENTARY TRACT AND METABOLISM</i> 77
<i>.ALIMENTARY TRACT AND METABOLISM</i>	77	
<i>Gastrogel (FM)</i>		<i>.ALIMENTARY TRACT AND METABOLISM</i> 60
<i>.ALIMENTARY TRACT AND METABOLISM</i>	60	
<i>Gastro-Stop Loperamide (AS)</i>		<i>.ALIMENTARY TRACT AND METABOLISM</i> 77
<i>.ALIMENTARY TRACT AND METABOLISM</i>	77	
<i>GAUZE AND COTTON TISSUE COMBINE ROLL</i>		<i>.Repatriation Schedule</i> 1286
<i>.Repatriation Schedule</i>	1286	

GENERIC/PROPRIETARY INDEX

<i>Gaviscon P (RC)</i>		.ANTIINFECTIVES FOR SYSTEMIC USE..... 234
.ALIMENTARY TRACT AND METABOLISM..... 67		<i>GenRx Cefaclor CD (GX)</i>
GEFITINIB		.ANTIINFECTIVES FOR SYSTEMIC USE..... 234
.ANTINEOPLASTIC AND IMMUNOMODULATING		<i>GenRx Cephalexin (GX)</i>
AGENTS 269		.ANTIINFECTIVES FOR SYSTEMIC USE..... 231, 232, 233
GELATIN-SUCCINYLATED		<i>GenRx Ciprofloxacin (GX)</i>
.BLOOD AND BLOOD FORMING ORGANS 119		.ANTIINFECTIVES FOR SYSTEMIC USE..... 242, 243
<i>Gelofusine (BR)</i>		<i>GenRx Clomipramine (GX)</i>
.BLOOD AND BLOOD FORMING ORGANS 119		.NERVOUS SYSTEM..... 563
GEMFIBROZIL		<i>GenRx Cyproterone Acetate (GX)</i>
.CARDIOVASCULAR SYSTEM 169		.ANTINEOPLASTIC AND IMMUNOMODULATING
<i>Gemfibrozil-GA (UA)</i>		AGENTS 295
.CARDIOVASCULAR SYSTEM 169		.GENITO URINARY SYSTEM AND SEX HORMONES 210,
<i>Gemhexal (SZ)</i>		211
.CARDIOVASCULAR SYSTEM 169		<i>GenRx Diltiazem CD (GX)</i>
<i>Generic Health Pty Ltd (GQ)</i>		.CARDIOVASCULAR SYSTEM 134
.NERVOUS SYSTEM..... 523, 524		<i>GenRx Doxycycline (GX)</i>
<i>Genlac (QA)</i>		.ANTIINFECTIVES FOR SYSTEMIC USE..... 223, 224
.ALIMENTARY TRACT AND METABOLISM..... 73		<i>GenRx Enalapril (GX)</i>
.Palliative Care 663		.CARDIOVASCULAR SYSTEM 135
<i>Genoptic (AG)</i>		<i>GenRx Famotidine (GX)</i>
.SENSORY ORGANS..... 605		.ALIMENTARY TRACT AND METABOLISM..... 60, 61
<i>Genotropin (PF)</i>		<i>GenRx Fluoxetine (GX)</i>
.Section 100 1204		.NERVOUS SYSTEM..... 567
<i>Genotropin GoQuick (PF)</i>		<i>GenRx Fosinopril (GX)</i>
.Section 100 1203		.CARDIOVASCULAR SYSTEM 136
<i>Genotropin MiniQuick (PF)</i>		<i>GenRx Frusemide (GX)</i>
.Section 100 1203, 1204		.CARDIOVASCULAR SYSTEM 126, 127
<i>Genox 10 (AF)</i>		<i>GenRx Gabapentin (GX)</i>
.ANTINEOPLASTIC AND IMMUNOMODULATING		.NERVOUS SYSTEM..... 531, 532
AGENTS 294		.Repatriation Schedule 1263, 1264
<i>Genox 20 (AF)</i>		<i>GenRx Gemfibrozil (GX)</i>
.ANTINEOPLASTIC AND IMMUNOMODULATING		.CARDIOVASCULAR SYSTEM 169
AGENTS 294		<i>GenRx Gliclazide (GX)</i>
<i>GenRx Aciclovir (GX)</i>		.ALIMENTARY TRACT AND METABOLISM..... 84
.ANTIINFECTIVES FOR SYSTEMIC USE..... 250, 251		<i>GenRx Indapamide (GX)</i>
<i>GenRx Allopurinol (GX)</i>		.CARDIOVASCULAR SYSTEM 126
.MUSCULO-SKELETAL SYSTEM 497		<i>GenRx Isosorbide Mononitrate (GX)</i>
<i>GenRx Alprazolam (GX)</i>		.CARDIOVASCULAR SYSTEM 124
.NERVOUS SYSTEM..... 560		<i>GenRx Lamotrigine (GX)</i>
<i>GenRx Amiodarone (GX)</i>		.NERVOUS SYSTEM..... 534
.CARDIOVASCULAR SYSTEM 122		<i>GenRx Meloxicam (GX)</i>
<i>GenRx Amoxycillin (GX)</i>		.MUSCULO-SKELETAL SYSTEM 491, 492
.ANTIINFECTIVES FOR SYSTEMIC USE..... 225, 226		<i>GenRx Metoprolol (GX)</i>
<i>GenRx Azathioprine (GX)</i>		.CARDIOVASCULAR SYSTEM 130
.ANTINEOPLASTIC AND IMMUNOMODULATING		<i>GenRx Mirtazapine (GX)</i>
AGENTS 489		.NERVOUS SYSTEM..... 572
<i>GenRx Baclofen (GX)</i>		<i>GenRx Moclobemide (GX)</i>
.MUSCULO-SKELETAL SYSTEM 496		.NERVOUS SYSTEM..... 569, 570
<i>GenRx Calcitriol (GX)</i>		<i>GenRx Nifedipine (GX)</i>
.ALIMENTARY TRACT AND METABOLISM..... 100		.CARDIOVASCULAR SYSTEM 133
.MUSCULO-SKELETAL SYSTEM 506		<i>GenRx Norfloxacin (GX)</i>
<i>GenRx Captopril (GX)</i>		.ANTIINFECTIVES FOR SYSTEMIC USE..... 243
.CARDIOVASCULAR SYSTEM 134		<i>GenRx Paroxetine (GX)</i>
<i>GenRx Cefaclor (GX)</i>		.NERVOUS SYSTEM..... 568

GENERIC/PROPRIETARY INDEX

<i>GenRx Perindopril/ Indapamide 4/1.25 (GX)</i>		
.CARDIOVASCULAR SYSTEM	142	
<i>GenRx Piroxicam (GX)</i>		
.MUSCULO-SKELETAL SYSTEM	492, 493	
<i>GenRx Ramipril (GX)</i>		
.CARDIOVASCULAR SYSTEM	139	
<i>GenRx Ranitidine (GX)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	61	
<i>GenRx Salbutamol (GX)</i>		
.Prescriber Bag	57, 58	
.RESPIRATORY SYSTEM	595	
<i>GenRx Sertraline (GX)</i>		
.NERVOUS SYSTEM.....	568	
<i>GenRx Simvastatin (GX)</i>		
.CARDIOVASCULAR SYSTEM	166, 167	
<i>GenRx Sotalol (GX)</i>		
.CARDIOVASCULAR SYSTEM	122	
<i>GenRx Tamoxifen (GX)</i>		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	294	
<i>GenRx Terbinafine (GX)</i>		
.DERMATOLOGICALS.....	192, 193	
.Repatriation Schedule.....	1251	
GENTAMICIN		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	240	
.SENSORY ORGANS.....	605	
<i>Genteal (AQ)</i>		
.SENSORY ORGANS.....	621	
<i>Genteal gel (AQ)</i>		
.SENSORY ORGANS.....	621	
GESTRINONE		
.GENITO URINARY SYSTEM AND SEX HORMONES .	211	
<i>Gilenya (NV)</i>		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	315	
GLATIRAMER ACETATE		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	303	
<i>Gliadel (OA)</i>		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	256	
GLIBENCLAMIDE		
.ALIMENTARY TRACT AND METABOLISM.....	84	
GLICLAZIDE		
.ALIMENTARY TRACT AND METABOLISM.....	84	
<i>Glimel (AF)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	84	
GLIMEPIRIDE		
.ALIMENTARY TRACT AND METABOLISM.....	84	
<i>Glimepiride AN (EA)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	84, 85	
<i>Glimepiride GA 1 (GN)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	85	
<i>Glimepiride GA 2 (GN)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	85	
<i>Glimepiride GA 3 (GN)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	85	
<i>Glimepiride GA 4 (GN)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	85	
<i>Glimepiride Sandoz (SZ)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	85	
GLIPIZIDE		
.ALIMENTARY TRACT AND METABOLISM.....	85	
<i>Glivec (NV)</i>		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	271, 272, 274, 275, 276, 277, 278, 279	
<i>GlucaGen Hypokit (NO)</i>		
.Prescriber Bag	56	
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX		
HORMONES AND INSULINS.....	220	
GLUCAGON HYDROCHLORIDE		
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX		
HORMONES AND INSULINS.....	220	
<i>Glucobay 100 (BN)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	90	
<i>Glucobay 50 (BN)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	90	
<i>Glucobete 1000 (DO)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	83	
<i>Glucobete 500 (DO)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	83	
<i>Glucobete 850 (DO)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	84	
<i>Glucodr (OZ)</i>		
.VARIOUS.....	630, 631	
<i>Glucoflex-R (NA)</i>		
.VARIOUS.....	630, 631	
<i>Glucophage (MQ)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	84	
GLUCOSE		
.BLOOD AND BLOOD FORMING ORGANS.....	119	
GLUCOSE AND KETONE INDICATOR URINE		
.VARIOUS.....	629	
GLUCOSE INDICATOR BLOOD		
.VARIOUS.....	629, 631, 632	
GLUCOSE INDICATOR URINE		
.VARIOUS.....	629	
<i>Glucovance 250mg/1.25mg (AL)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	87	
<i>Glucovance 500mg/2.5mg (AL)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	87	
<i>Glucovance 500mg/5mg (AL)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	87	
<i>GluNEO (IF)</i>		
.VARIOUS.....	630, 631	
<i>Glyade (AF)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	84	
<i>Glyade MR (AF)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	84	
GLYCEROL		

GENERIC/PROPRIETARY INDEX

.ALIMENTARY TRACT AND METABOLISM.....	75
.Palliative Care	666
.Repatriation Schedule	1245
GLYCERYL TRINITRATE	
.CARDIOVASCULAR SYSTEM	123
GLYCINE WITH CARBOHYDRATE	
.VARIOUS.....	657
<i>Glycine500 (VF)</i>	
.VARIOUS.....	657
GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS	
.VARIOUS.....	657
GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS	
.VARIOUS.....	657
GLYCOPYRRONIUM	
.RESPIRATORY SYSTEM	601
<i>Glycosade (VF)</i>	
.VARIOUS.....	649
<i>GN-Carvedilol (GN)</i>	
.CARDIOVASCULAR SYSTEM	131, 132
<i>Gold Cross (BI)</i>	
.Repatriation Schedule	1261, 1267, 1268
GOLIMUMAB	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	456, 463, 466, 471, 474, 477
GONADOTROPHIN CHORIONIC HUMAN	
.GENITO URINARY SYSTEM AND SEX HORMONES .	210
.Section 100	1206
GONADOTROPHIN-MENOPAUSAL HUMAN	
.Section 100	1206
<i>Gonal-f Pen (SG)</i>	
.GENITO URINARY SYSTEM AND SEX HORMONES .	209
.Section 100	1205
<i>GoodLife (JN)</i>	
.VARIOUS.....	629, 631
<i>Gopten (GO)</i>	
.CARDIOVASCULAR SYSTEM	140
GOSERELIN	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	292
GOSERELIN (&) BICALUTAMIDE	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	292
GRANISETRON	
.ALIMENTARY TRACT AND METABOLISM.....	68
<i>Granisetron Kabi (PK)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	68
<i>Granisetron-AFT (AE)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	68
<i>Granocyte 13 (HH)</i>	
.Section 100	762, 1019
<i>Granocyte 34 (HH)</i>	
.Section 100	762, 1019
GRISEOFULVIN	
.DERMATOLOGICALS.....	192

<i>Grisovin (QA)</i>	
.DERMATOLOGICALS	192
<i>Grisovin 500 (QA)</i>	
.DERMATOLOGICALS	192
<i>Gynotril (ER)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	298

H

<i>Haldol decanoate (JC)</i>	
.NERVOUS SYSTEM.....	545
HALOPERIDOL	
.NERVOUS SYSTEM.....	544
HALOPERIDOL DECANOATE	
.NERVOUS SYSTEM.....	544
<i>Hamilton Skin Therapy Oil (KY)</i>	
.Repatriation Schedule	1251
<i>Hamilton Skin Therapy Wash (KY)</i>	
.Repatriation Schedule	1254
<i>Handy 36361414 (BV)</i>	
.Repatriation Schedule	1273
<i>Handy 71117-05 (BV)</i>	
.Repatriation Schedule	1280
<i>Handy 71117-06 (BV)</i>	
.Repatriation Schedule	1280
<i>Handygauze Cohesive 8631 (BV)</i>	
.Repatriation Schedule	1274
<i>Handygauze Cohesive 8633 (BV)</i>	
.Repatriation Schedule	1274
<i>Handygauze Cohesive 8635 (BV)</i>	
.Repatriation Schedule	1274
<i>HCU Anamix infant (SB)</i>	
.VARIOUS.....	652
<i>HCU Anamix junior LQ (SB)</i>	
.VARIOUS.....	650
<i>HCU cooler 10 (VF)</i>	
.VARIOUS.....	652
<i>HCU cooler 15 (VF)</i>	
.VARIOUS.....	652
<i>HCU cooler 20 (VF)</i>	
.VARIOUS.....	652
<i>HCU express 15 (VF)</i>	
.VARIOUS.....	652
<i>HCU gel (VF)</i>	
.VARIOUS.....	652
<i>HCU Lophlex LQ 20 (SB)</i>	
.VARIOUS.....	652
<i>Healthpro (IF)</i>	
.VARIOUS.....	630, 631
HEPARIN SODIUM	
.BLOOD AND BLOOD FORMING ORGANS.....	105
<i>Hepsera (GI)</i>	
.Section 100.....	745, 1001
<i>Herron ClearLax (ON)</i>	

GENERIC/PROPRIETARY INDEX

.ALIMENTARY TRACT AND METABOLISM.....	74	.ALIMENTARY TRACT AND METABOLISM.....	82
.Palliative Care	664	<i>Hycor (QA)</i>	
HEXAMINE HIPPURATE		.SENSORY ORGANS.....	607
.ANTIINFECTIVES FOR SYSTEMIC USE.....	245	<i>Hydopa (AF)</i>	
HIGH FAT FORMULA WITH VITAMINS, MINERALS AND		.CARDIOVASCULAR SYSTEM	125
TRACE ELEMENTS AND LOW IN PROTEIN AND		HYDRALAZINE	
CARBOHYDRATE		.CARDIOVASCULAR SYSTEM	125
.VARIOUS.....	657, 658	<i>Hydrea (BQ)</i>	
<i>Hiprex (IA)</i>		.ANTINEOPLASTIC AND IMMUNOMODULATING	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	245	AGENTS	291
HOMATROPINE		<i>Hydrene 25/50 (AF)</i>	
.SENSORY ORGANS.....	614	.CARDIOVASCULAR SYSTEM	128
<i>Hospira Cefazolin Sodium (HH)</i>		HYDROCHLOROTHIAZIDE	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	233	.CARDIOVASCULAR SYSTEM	126
<i>Hospira Ceftriaxone (HH)</i>		HYDROCHLOROTHIAZIDE + AMILORIDE	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	236	.CARDIOVASCULAR SYSTEM	127
<i>Hospira Pty Limited (HH)</i>		HYDROCHLOROTHIAZIDE + TRIAMTERENE	
.ALIMENTARY TRACT AND METABOLISM.....	72	.CARDIOVASCULAR SYSTEM	128
.ANTIINFECTIVES FOR SYSTEMIC USE....	228, 233, 235,	<i>Hydrocoll 900744 (HR)</i>	
236, 242, 243, 244		.Repatriation Schedule	1283
.ANTINEOPLASTIC AND IMMUNOMODULATING		<i>Hydrocoll 900936 (HR)</i>	
AGENTS	258, 489	.Repatriation Schedule	1283
.BLOOD AND BLOOD FORMING ORGANS	105	<i>Hydrocoll Thin 900758 (HR)</i>	
.NERVOUS SYSTEM.....	514, 560	.Repatriation Schedule	1282
.Prescriber Bag	56, 57	HYDROCORTISONE	
.RESPIRATORY SYSTEM	604	.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX	
.Section 100	736, 933, 991, 1196	HORMONES AND INSULINS.....	217
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX		HYDROCORTISONE ACETATE	
HORMONES AND INSULINS.....	216, 217	.ALIMENTARY TRACT AND METABOLISM.....	77
<i>HPMC PAA (IQ)</i>		.DERMATOLOGICALS	195
.SENSORY ORGANS.....	621	.SENSORY ORGANS.....	607
<i>Humalog (LY)</i>		HYDROCORTISONE SODIUM SUCCINATE	
.ALIMENTARY TRACT AND METABOLISM.....	81	.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX	
<i>Humalog KwikPen (KP)</i>		HORMONES AND INSULINS.....	217
.ALIMENTARY TRACT AND METABOLISM.....	81	HYDROMORPHONE	
<i>Humalog Mix25 (LY)</i>		.NERVOUS SYSTEM.....	511, 512
.ALIMENTARY TRACT AND METABOLISM.....	82	<i>Hydrosorb 900854 (HR)</i>	
<i>Humalog Mix25 KwikPen (KP)</i>		.Repatriation Schedule	1285
.ALIMENTARY TRACT AND METABOLISM.....	83	<i>Hydroxo-B12 (AS)</i>	
<i>Humalog Mix50 (LY)</i>		.BLOOD AND BLOOD FORMING ORGANS.....	119
.ALIMENTARY TRACT AND METABOLISM.....	83	HYDROXOCOBALAMIN	
<i>Humalog Mix50 KwikPen (KP)</i>		.BLOOD AND BLOOD FORMING ORGANS.....	119
.ALIMENTARY TRACT AND METABOLISM.....	83	HYDROXYCHLOROQUINE	
<i>Humatrope (LY)</i>		.MUSCULO-SKELETAL SYSTEM	495
.Section 100	1203, 1204	<i>Hydroxychloroquine Actavis (GN)</i>	
<i>Humira (VE)</i>		.MUSCULO-SKELETAL SYSTEM	495
.ANTINEOPLASTIC AND IMMUNOMODULATING		HYDROXYUREA	
AGENTS	323, 326, 329, 332, 339, 342, 346, 349,	.ANTINEOPLASTIC AND IMMUNOMODULATING	
353, 356, 362, 367, 372, 375		AGENTS	291
.Section 100	811, 1070	<i>Hygroton 25 (LM)</i>	
<i>Humulin 30/70 (LY)</i>		.CARDIOVASCULAR SYSTEM	126
.ALIMENTARY TRACT AND METABOLISM.....	82	<i>Hylo-Forte (AE)</i>	
<i>Humulin NPH (LY)</i>		.SENSORY ORGANS.....	623, 624
.ALIMENTARY TRACT AND METABOLISM.....	82	<i>Hylo-Fresh (AE)</i>	
<i>Humulin R (LY)</i>		.SENSORY ORGANS.....	623, 624

GENERIC/PROPRIETARY INDEX

HYOSCINE BUTYLBROMIDE		
.Palliative Care	662	
.Repatriation Schedule	1244	
<i>Hypnodorm (AF)</i>		
.Repatriation Schedule	1264	
HYPROMELLOSE		
.SENSORY ORGANS	621	
HYPROMELLOSE + CARBOMER-980		
.SENSORY ORGANS	621	
<i>Hypurin Isophane (AS)</i>		
.ALIMENTARY TRACT AND METABOLISM	82	
<i>Hypurin Neutral (AS)</i>		
.ALIMENTARY TRACT AND METABOLISM	82	
<i>Hysone 20 (AF)</i>		
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX		
HORMONES AND INSULINS	217	
<i>Hysone 4 (AF)</i>		
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX		
HORMONES AND INSULINS	217	
<i>Hytrin (GO)</i>		
.Repatriation Schedule	1258	
I		
<i>Ialex (LN)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE	231, 232, 233	
IBANDRONIC ACID		
.MUSCULO-SKELETAL SYSTEM	499	
.Section 100	918, 1176	
<i>Ibilex 125 (AF)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE	231	
<i>Ibilex 250 (AF)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE	231, 232, 233	
<i>Ibilex 500 (AF)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE	232	
<i>Ibimicyn (GN)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE	227	
IBUPROFEN		
.MUSCULO-SKELETAL SYSTEM	493	
.Palliative Care	668	
ICATIBANT		
.BLOOD AND BLOOD FORMING ORGANS	120	
ICHTHAMMOL		
.Repatriation Schedule	1254	
ICHTHAMMOL + ZINC OXIDE		
.Repatriation Schedule	1254	
<i>Idaprex 2 (SZ)</i>		
.CARDIOVASCULAR SYSTEM	137	
<i>Idaprex 4 (SZ)</i>		
.CARDIOVASCULAR SYSTEM	137	
<i>Idaprex 8 (SZ)</i>		
.CARDIOVASCULAR SYSTEM	137	
<i>Idaprex Combi 4/1.25 (SZ)</i>		
.CARDIOVASCULAR SYSTEM	142	
IDARUBICIN		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	259	
<i>Ikorel (SW)</i>		
.CARDIOVASCULAR SYSTEM	124	
<i>Ikotab (QA)</i>		
.CARDIOVASCULAR SYSTEM	124	
ILOPROST		
.Section 100	710, 965	
IMATINIB		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	270, 271, 272, 274, 275, 276, 277, 278	
<i>Imazan (ER)</i>		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	489	
<i>Imdur 120 mg (AP)</i>		
.CARDIOVASCULAR SYSTEM	123	
<i>Imdur Durule (AP)</i>		
.CARDIOVASCULAR SYSTEM	124	
<i>Imigran (AS)</i>		
.NERVOUS SYSTEM	526	
<i>Imigran (LN)</i>		
.NERVOUS SYSTEM	526	
<i>Imigran FDT (AS)</i>		
.NERVOUS SYSTEM	526	
IMIPRAMINE		
.NERVOUS SYSTEM	564	
IMIQUIMOD		
.DERMATOLOGICALS	198	
.Repatriation Schedule	1254	
<i>ImmuCyst (SW)</i>		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	303	
<i>Imodium (JT)</i>		
.ALIMENTARY TRACT AND METABOLISM	77	
<i>Imovane (SW)</i>		
.Repatriation Schedule	1265	
<i>Implanon NXT (MK)</i>		
.GENITO URINARY SYSTEM AND SEX HORMONES .	202	
<i>Imrest (AF)</i>		
.Repatriation Schedule	1265	
<i>Imtrate 60 mg (GN)</i>		
.CARDIOVASCULAR SYSTEM	124	
<i>Imukin (BY)</i>		
.Section 100	764, 1021	
<i>Imuran (AS)</i>		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	489	
<i>In a Wink Moisturising (IQ)</i>		
.SENSORY ORGANS	621	
<i>Incivo (JC)</i>		
.Section 100	744, 1000	
INCOBOTULINUMTOXINA		
.Section 100	1202	
<i>Incruse Ellipta (GK)</i>		
.RESPIRATORY SYSTEM	602	

GENERIC/PROPRIETARY INDEX

INDACATEROL		
.RESPIRATORY SYSTEM	594	
INDACATEROL + GLYCOPYRRONIUM		
.RESPIRATORY SYSTEM	599	
INDAPAMIDE		
.CARDIOVASCULAR SYSTEM	126	
<i>Indapamide AN (EA)</i>		
.CARDIOVASCULAR SYSTEM	126	
<i>Indapamide Sandoz (SZ)</i>		
.CARDIOVASCULAR SYSTEM	126	
<i>Indapamide-GA (GN)</i>		
.CARDIOVASCULAR SYSTEM	126	
<i>Inderal (AP)</i>		
.CARDIOVASCULAR SYSTEM	128	
INDINAVIR		
.Section 100	740, 997	
<i>Indocid (AS)</i>		
.MUSCULO-SKELETAL SYSTEM	491	
.Palliative Care	668	
INDOMETHACIN		
.MUSCULO-SKELETAL SYSTEM	490, 491	
.Palliative Care	668	
<i>Indopril 2 (QA)</i>		
.CARDIOVASCULAR SYSTEM	137	
<i>Indopril 4 (QA)</i>		
.CARDIOVASCULAR SYSTEM	137	
<i>Indopril 8 (QA)</i>		
.CARDIOVASCULAR SYSTEM	137	
<i>Indosyl Combi 4/1.25 (QA)</i>		
.CARDIOVASCULAR SYSTEM	142	
<i>Indosyl Mono 2 (FM)</i>		
.CARDIOVASCULAR SYSTEM	137	
<i>Indosyl Mono 4 (FM)</i>		
.CARDIOVASCULAR SYSTEM	137	
<i>Indosyl Mono 8 (FM)</i>		
.CARDIOVASCULAR SYSTEM	137	
INFLIXIMAB		
.Repatriation Schedule	1260	
.Section 100 ... 820, 824, 834, 840, 847, 849, 859, 865,		
1078, 1079, 1082, 1088, 1098, 1100, 1107, 1117,		
1123		
INGENOL MEBUTATE		
.Repatriation Schedule	1252	
<i>iNova Pharmaceuticals (Australia) Pty Ltd (IA)</i>		
.NERVOUS SYSTEM	590	
<i>Insig (QA)</i>		
.CARDIOVASCULAR SYSTEM	126	
<i>Inspira (PF)</i>		
.CARDIOVASCULAR SYSTEM	127	
INSULIN ASPART		
.ALIMENTARY TRACT AND METABOLISM	81	
INSULIN ASPART + INSULIN ASPART PROTAMINE		
.ALIMENTARY TRACT AND METABOLISM	82	
INSULIN DETEMIR		
.ALIMENTARY TRACT AND METABOLISM	83	
INSULIN GLARGINE		
.ALIMENTARY TRACT AND METABOLISM	83	
INSULIN GLULISINE		
.ALIMENTARY TRACT AND METABOLISM	81	
INSULIN ISOPHANE BOVINE		
.ALIMENTARY TRACT AND METABOLISM	82	
INSULIN ISOPHANE HUMAN		
.ALIMENTARY TRACT AND METABOLISM	82	
INSULIN ISOPHANE HUMAN + INSULIN NEUTRAL		
HUMAN		
.ALIMENTARY TRACT AND METABOLISM	82	
INSULIN LISPRO		
.ALIMENTARY TRACT AND METABOLISM	81	
INSULIN LISPRO + INSULIN LISPRO PROTAMINE		
.ALIMENTARY TRACT AND METABOLISM	82	
INSULIN NEUTRAL BOVINE		
.ALIMENTARY TRACT AND METABOLISM	82	
INSULIN NEUTRAL HUMAN		
.ALIMENTARY TRACT AND METABOLISM	82	
<i>Intal CFC-Free (SW)</i>		
.RESPIRATORY SYSTEM	602	
<i>Intal Forte CFC-Free (SW)</i>		
.RESPIRATORY SYSTEM	602	
<i>Intal Spincaps (GN)</i>		
.RESPIRATORY SYSTEM	602	
<i>Integrilin (MK)</i>		
.BLOOD AND BLOOD FORMING ORGANS	109	
<i>Intelence (JC)</i>		
.Section 100	750, 1007	
INTERFERON ALFA-2A		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	299, 300	
.Section 100	762, 1020	
INTERFERON ALFA-2B		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	300	
.Section 100	763, 1021	
INTERFERON BETA-1A		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	301	
INTERFERON BETA-1B		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	301	
INTERFERON GAMMA-1B		
.Section 100	763, 1021	
<i>Intrasite Gel 7313 (SN)</i>		
.Repatriation Schedule	1284	
<i>Intron A (MK)</i>		
.Section 100	763, 1021	
<i>Intron A Redipen (MK)</i>		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	300	
.Section 100	763, 1021	
<i>Invega (JC)</i>		
.NERVOUS SYSTEM	555	

GENERIC/PROPRIETARY INDEX

<i>Invega Sustenna</i> (JC)			
.NERVOUS SYSTEM.....	555	<i>Irbesartan HCT Actavis 300/12.5</i> (UA)	
<i>Invirase</i> (RO)		.CARDIOVASCULAR SYSTEM	149
.Section 100	741, 998	<i>Irbesartan HCT Actavis 300/25</i> (UA)	
<i>Invokana</i> (JC)		.CARDIOVASCULAR SYSTEM	149
.ALIMENTARY TRACT AND METABOLISM.....	97	<i>Irbesartan HCT GH 150/12.5</i> (GQ)	
<i>Inza 250</i> (AF)		.CARDIOVASCULAR SYSTEM	149
.MUSCULO-SKELETAL SYSTEM	493	<i>Irbesartan HCT GH 300/12.5</i> (GQ)	
.Palliative Care	669	.CARDIOVASCULAR SYSTEM	149
<i>Inza 500</i> (AF)		<i>Irbesartan HCT GH 300/25</i> (GQ)	
.MUSCULO-SKELETAL SYSTEM	493	.CARDIOVASCULAR SYSTEM	149
.Palliative Care	669	<i>Irbesartan HCT Winthrop 150/12.5</i> (WA)	
<i>Iodosorb 66051330</i> (SN)		.CARDIOVASCULAR SYSTEM	149
.Repatriation Schedule.....	1276	<i>Irbesartan HCT Winthrop 300/12.5</i> (WA)	
<i>Iodosorb 66051340</i> (SN)		.CARDIOVASCULAR SYSTEM	149
.Repatriation Schedule.....	1276	<i>Irbesartan HCT Winthrop 300/25</i> (WA)	
<i>Iodosorb 66051360</i> (SN)		.CARDIOVASCULAR SYSTEM	149
.Repatriation Schedule.....	1276	<i>Irbesartan HCTZ AN 150/12.5</i> (EA)	
<i>Iodosorb Ointment 66051230</i> (SN)		.CARDIOVASCULAR SYSTEM	149
.Repatriation Schedule.....	1276	<i>Irbesartan HCTZ AN 300/12.5</i> (EA)	
<i>Iodosorb Ointment 66051240</i> (SN)		.CARDIOVASCULAR SYSTEM	149
.Repatriation Schedule.....	1276	<i>Irbesartan HCTZ AN 300/25</i> (EA)	
<i>Iodosorb Powder 66051070</i> (SN)		.CARDIOVASCULAR SYSTEM	150
.Repatriation Schedule.....	1276	<i>Irbesartan HCTZ-GA 150/12.5</i> (GN)	
<i>Ionil-T</i> (GA)		.CARDIOVASCULAR SYSTEM	149
.Repatriation Schedule.....	1253	<i>Irbesartan HCTZ-GA 300/12.5</i> (GN)	
<i>Iopidine 0.5%</i> (AQ)		.CARDIOVASCULAR SYSTEM	149
.SENSORY ORGANS.....	608	<i>Irbesartan HCTZ-GA 300/25</i> (GN)	
<i>I-Pantoprazole</i> (CR)		.CARDIOVASCULAR SYSTEM	150
.ALIMENTARY TRACT AND METABOLISM.....	65	<i>Irbesartan RBX</i> (RA)	
<i>Ipratrin</i> (AF)		.CARDIOVASCULAR SYSTEM	145, 146
.RESPIRATORY SYSTEM	601	<i>Irbesartan Sandoz</i> (SZ)	
<i>Ipratrin Adult</i> (AF)		.CARDIOVASCULAR SYSTEM	145, 146
.RESPIRATORY SYSTEM	601	<i>Irbesartan Winthrop</i> (WA)	
IPRATROPIUM		.CARDIOVASCULAR SYSTEM	145, 146
.Repatriation Schedule.....	1267	<i>Irbesartan/HCT Sandoz</i> (SZ)	
.RESPIRATORY SYSTEM	601	.CARDIOVASCULAR SYSTEM	149
<i>Iptam</i> (AL)		<i>Irbesartan/HCTZ RBX 150/12.5</i> (RA)	
.NERVOUS SYSTEM.....	526	.CARDIOVASCULAR SYSTEM	149
IRBESARTAN		<i>Irbesartan/HCTZ RBX 300/12.5</i> (RA)	
.CARDIOVASCULAR SYSTEM	145	.CARDIOVASCULAR SYSTEM	149
IRBESARTAN + HYDROCHLOROTHIAZIDE		<i>Irbesartan/HCTZ RBX 300/25</i> (RA)	
.CARDIOVASCULAR SYSTEM	148	.CARDIOVASCULAR SYSTEM	149
<i>Irbesartan Actavis 150</i> (UA)		<i>Irbesartan-DRLA</i> (RZ)	
.CARDIOVASCULAR SYSTEM	145	.CARDIOVASCULAR SYSTEM	145
<i>Irbesartan Actavis 300</i> (UA)		<i>Irbesartan-GA</i> (GN)	
.CARDIOVASCULAR SYSTEM	145	.CARDIOVASCULAR SYSTEM	145
<i>Irbesartan Actavis 75</i> (UA)		<i>Ircal</i> (PE)	
.CARDIOVASCULAR SYSTEM	145	.SENSORY ORGANS.....	621, 622
<i>Irbesartan AN</i> (EA)		<i>Iressa</i> (AP)	
.CARDIOVASCULAR SYSTEM	145	.ANTINEOPLASTIC AND IMMUNOMODULATING	
<i>Irbesartan GH</i> (GQ)		AGENTS	270
.CARDIOVASCULAR SYSTEM	145, 146	IRON	
<i>Irbesartan HCT Actavis 150/12.5</i> (UA)		.BLOOD AND BLOOD FORMING ORGANS.....	118
.CARDIOVASCULAR SYSTEM	149	IRON POLYMALTOSE	
		.BLOOD AND BLOOD FORMING ORGANS.....	118

GENERIC/PROPRIETARY INDEX

IRON SUCROSE	
.BLOOD AND BLOOD FORMING ORGANS	118
<i>Irprestan 150 (ZP)</i>	
.CARDIOVASCULAR SYSTEM	145
<i>Irprestan 300 (ZP)</i>	
.CARDIOVASCULAR SYSTEM	145
<i>Irprestan 75 (ZP)</i>	
.CARDIOVASCULAR SYSTEM	146
<i>Iscover (AV)</i>	
.BLOOD AND BLOOD FORMING ORGANS	106, 107
.Repatriation Schedule	1248
<i>Isentress (MK)</i>	
.Section 100	755, 1012, 1013
<i>Isoleucine 1000 (VF)</i>	
.VARIOUS	658
<i>Isoleucine 50 (VF)</i>	
.VARIOUS	658
ISOLEUCINE WITH CARBOHYDRATE	
.VARIOUS	658
<i>Isomonit (SZ)</i>	
.CARDIOVASCULAR SYSTEM	124
ISONIAZID	
.ANTIINFECTIVES FOR SYSTEMIC USE	249
<i>Isoptin (GO)</i>	
.CARDIOVASCULAR SYSTEM	134
<i>Isoptin 180 SR (GO)</i>	
.CARDIOVASCULAR SYSTEM	133
<i>Isoptin SR (GO)</i>	
.CARDIOVASCULAR SYSTEM	134
<i>Isopto Carpine (AQ)</i>	
.SENSORY ORGANS	609
<i>Isopto Homatropine (AQ)</i>	
.SENSORY ORGANS	614
<i>Isordil Sublingual (QA)</i>	
.CARDIOVASCULAR SYSTEM	123
<i>Isosorbide AN (EA)</i>	
.CARDIOVASCULAR SYSTEM	124
ISOSORBIDE DINITRATE	
.CARDIOVASCULAR SYSTEM	123
ISOSORBIDE MONONITRATE	
.CARDIOVASCULAR SYSTEM	123
ISOTRETINOIN	
.DERMATOLOGICALS	197
<i>Isotretinoin AN (EA)</i>	
.DERMATOLOGICALS	197, 198
<i>Isotretinoin SCP 10 (CR)</i>	
.DERMATOLOGICALS	197
<i>Isotretinoin SCP 20 (CR)</i>	
.DERMATOLOGICALS	198
ISPAGHULA HUSK DRY	
.Repatriation Schedule	1245
ITRACONAZOLE	
.ANTIINFECTIVES FOR SYSTEMIC USE	246
IVABRADINE	
.CARDIOVASCULAR SYSTEM	124

IVACAFTOR	
.Section 100	929, 1192
IVERMECTIN	
.ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS	592, 593

J

<i>Janumet (MK)</i>	
.ALIMENTARY TRACT AND METABOLISM	89
<i>Janumet XR (MK)</i>	
.ALIMENTARY TRACT AND METABOLISM	89
<i>Januvia (MK)</i>	
.ALIMENTARY TRACT AND METABOLISM	95
<i>Jardiance (BY)</i>	
.ALIMENTARY TRACT AND METABOLISM	99
<i>Jelonet 7404 (SN)</i>	
.Repatriation Schedule	1280
<i>Jezil (GN)</i>	
.CARDIOVASCULAR SYSTEM	169
<i>JJ 12010 (JJ)</i>	
.Repatriation Schedule	1286
<i>Jurnista (JC)</i>	
.NERVOUS SYSTEM	512

K

<i>Kaletra (VE)</i>	
.Section 100	753, 1010
<i>Kalixocin (AF)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE	238
<i>Kalma 0.25 (AF)</i>	
.NERVOUS SYSTEM	560
<i>Kalma 0.5 (AF)</i>	
.NERVOUS SYSTEM	560
<i>Kalma 1 (AF)</i>	
.NERVOUS SYSTEM	560
<i>Kalma 2 (AF)</i>	
.NERVOUS SYSTEM	560
<i>Kaltostat 168117 (CC)</i>	
.Repatriation Schedule	1277
<i>Kaltostat 168210 (CC)</i>	
.Repatriation Schedule	1277
<i>Kaltostat 168212 (CC)</i>	
.Repatriation Schedule	1277
<i>Kalydeco (VR)</i>	
.Section 100	932, 1195
<i>Kapanol (YN)</i>	
.NERVOUS SYSTEM	512
<i>Kaptan (ER)</i>	
.NERVOUS SYSTEM	552, 553, 554
<i>Karbesat 150 (QA)</i>	
.CARDIOVASCULAR SYSTEM	145
<i>Karbesat 300 (QA)</i>	
.CARDIOVASCULAR SYSTEM	145

GENERIC/PROPRIETARY INDEX

<i>Karbesat 75 (QA)</i>		.NERVOUS SYSTEM.....535
.CARDIOVASCULAR SYSTEM.....	146	
<i>Karicare Aptamil Gold De-Lact (NU)</i>		<i>keyomega (VF)</i>
.VARIOUS.....	649, 650	.VARIOUS.....655
<i>Karicare Aptamil Pepti-Junior Gold (NU)</i>		<i>Kindergen (SB)</i>
.VARIOUS.....	648	.VARIOUS.....660
<i>Karlor CD (LN)</i>		<i>Kinson (AF)</i>
.ANTIINFECTIVES FOR SYSTEMIC USE.....	234	.NERVOUS SYSTEM.....539
<i>Karvea (SW)</i>		<i>Kivexa (VI)</i>
.CARDIOVASCULAR SYSTEM.....	145, 146	.Section 100.....751, 1008
<i>Karvezide 150/12.5 (SW)</i>		<i>Klacid (GO)</i>
.CARDIOVASCULAR SYSTEM.....	149	.ANTIINFECTIVES FOR SYSTEMIC USE.....238
<i>Karvezide 300/12.5 (SW)</i>		.Section 100.....737, 993
.CARDIOVASCULAR SYSTEM.....	149	<i>Kombiglyze XR 2.5/1000 (AP)</i>
<i>Karvezide 300/25 (SW)</i>		.ALIMENTARY TRACT AND METABOLISM.....88
.CARDIOVASCULAR SYSTEM.....	150	<i>Kombiglyze XR 5/1000 (AP)</i>
<i>Keflex (AS)</i>		.ALIMENTARY TRACT AND METABOLISM.....88
.ANTIINFECTIVES FOR SYSTEMIC USE.....	231, 232, 233	<i>Kombiglyze XR 5/500 (AP)</i>
<i>Keflor (AF)</i>		.ALIMENTARY TRACT AND METABOLISM.....88
.ANTIINFECTIVES FOR SYSTEMIC USE.....	234	<i>Konakion MM (RO)</i>
<i>Keflor CD (AF)</i>		.Prescriber Bag 57
.ANTIINFECTIVES FOR SYSTEMIC USE.....	234	<i>Kosteo (QA)</i>
<i>Kenacomb Otic (QA)</i>		.ALIMENTARY TRACT AND METABOLISM.....100
.SENSORY ORGANS.....	625	.MUSCULO-SKELETAL SYSTEM 506
<i>Kenacort-A10 (QA)</i>		<i>Krypton 2.5 (AF)</i>
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX		.GENITO URINARY SYSTEM AND SEX HORMONES 200,
HORMONES AND INSULINS.....	218, 219	201
<i>Kepcet (GN)</i>		.NERVOUS SYSTEM.....541
.NERVOUS SYSTEM.....	535	<i>KSART HCT 150/12.5 (QA)</i>
<i>Keppra (UC)</i>		.CARDIOVASCULAR SYSTEM.....149
.NERVOUS SYSTEM.....	535, 536	<i>KSART HCT 300/12.5 (QA)</i>
<i>Kerron 1000 (DO)</i>		.CARDIOVASCULAR SYSTEM.....149
.NERVOUS SYSTEM.....	535	<i>KSART HCT 300/25 (QA)</i>
<i>Kerron 250 (DO)</i>		.CARDIOVASCULAR SYSTEM.....150
.NERVOUS SYSTEM.....	535	<i>Kudeq (FZ)</i>
<i>Kerron 500 (DO)</i>		.MUSCULO-SKELETAL SYSTEM 495
.NERVOUS SYSTEM.....	535	<i>Kuvan (SG)</i>
<i>KetoCal 3</i>		.ALIMENTARY TRACT AND METABOLISM.....102, 103
1 (SB)		<i>Kytril (RO)</i>
.VARIOUS.....	657	.ALIMENTARY TRACT AND METABOLISM.....68
<i>KetoCal 4</i>		
1 (SB)		
.VARIOUS.....	658	
1 LQ (SB)		
.VARIOUS.....	657	
KETOCONAZOLE		
.DERMATOLOGICALS.....	192	
.Repatriation Schedule.....	1250	
<i>Keto-Diabor- Test 5000 (RD)</i>		
.VARIOUS.....	629	
<i>Keto-Diastix (BN)</i>		
.VARIOUS.....	629	
KETOPROFEN		
.MUSCULO-SKELETAL SYSTEM.....	493	
<i>Kevtam (AF)</i>		

L

LABETALOL	
.CARDIOVASCULAR SYSTEM.....	132
LACOSAMIDE	
.NERVOUS SYSTEM.....	532, 533
LACTATE + SODIUM CHLORIDE + POTASSIUM CHLORIDE	
+ CALCIUM CHLORIDE DIHYDRATE	
.BLOOD AND BLOOD FORMING ORGANS.....	120
LACTIC ACID + SALICYLIC ACID	
.Repatriation Schedule.....	1253
LACTULOSE	
.ALIMENTARY TRACT AND METABOLISM.....	73
.Palliative Care.....	663
<i>Lamictal (AS)</i>	

GENERIC/PROPRIETARY INDEX

.NERVOUS SYSTEM.....	534, 535	<i>Lanoxin-PG (QA)</i>	
<i>Lamidus (RA)</i>		.CARDIOVASCULAR SYSTEM	121
.NERVOUS SYSTEM.....	534	LANREOTIDE	
<i>Lamisil (NC)</i>		.Section 100.....	734, 989
.DERMATOLOGICALS.....	192	LANSOPRAZOLE	
.Repatriation Schedule	1250	.ALIMENTARY TRACT AND METABOLISM.....	62, 63
<i>Lamisil (Novartis Pharmaceuticals Australia Pty Limited)</i>		<i>Lansoprazole ODT GH (GQ)</i>	
(NV)		.ALIMENTARY TRACT AND METABOLISM.....	62, 63
.DERMATOLOGICALS.....	193	LANTHANUM	
.Repatriation Schedule	1251	.Section 100.....	933, 1196
<i>Lamisil DermGel (NC)</i>		.VARIOUS.....	626
.Repatriation Schedule	1250	<i>Lantus (SW)</i>	
LAMIVUDINE		.ALIMENTARY TRACT AND METABOLISM.....	83
.Section 100	746, 1003	<i>Lantus SoloStar (AV)</i>	
LAMIVUDINE + ZIDOVUDINE		.ALIMENTARY TRACT AND METABOLISM.....	83
.Section 100	752, 1009	<i>Lanvis (AS)</i>	
<i>Lamivudine 150 mg + Zidovudine 300 mg Alphapharm</i>		.ANTINEOPLASTIC AND IMMUNOMODULATING	
(AF)		AGENTS	258
.Section 100	753, 1010	<i>Lanzek (EL)</i>	
<i>Lamivudine Alphapharm (AF)</i>		.NERVOUS SYSTEM.....	547, 549, 550, 551
.Section 100	746, 1003	<i>Lanzek Zydis (EL)</i>	
<i>Lamivudine RBX (RA)</i>		.NERVOUS SYSTEM.....	547, 551
.Section 100	746, 1003	<i>Lanzopran (RA)</i>	
<i>Lamogine (AF)</i>		.ALIMENTARY TRACT AND METABOLISM.....	63
.NERVOUS SYSTEM.....	534	LAPATINIB	
LAMOTRIGINE		.ANTINEOPLASTIC AND IMMUNOMODULATING	
.NERVOUS SYSTEM.....	533	AGENTS	279
<i>Lamotrigine AN (EA)</i>		<i>Largactil (SW)</i>	
.NERVOUS SYSTEM.....	534	.NERVOUS SYSTEM.....	544
<i>Lamotrigine Aspen 100 (FM)</i>		.Prescriber Bag	56
.NERVOUS SYSTEM.....	534	<i>Lasix (SW)</i>	
<i>Lamotrigine Aspen 200 (FM)</i>		.CARDIOVASCULAR SYSTEM	126
.NERVOUS SYSTEM.....	534	.Prescriber Bag	56
<i>Lamotrigine Aspen 25 (FM)</i>		<i>Lasix-M (SW)</i>	
.NERVOUS SYSTEM.....	534	.CARDIOVASCULAR SYSTEM	127
<i>Lamotrigine Aspen 5 (FM)</i>		<i>Latanocom (FZ)</i>	
.NERVOUS SYSTEM.....	534	.SENSORY ORGANS.....	613
<i>Lamotrigine Aspen 50 (FM)</i>		LATANOPROST	
.NERVOUS SYSTEM.....	535	.SENSORY ORGANS.....	612
<i>Lamotrigine generichealth (GQ)</i>		LATANOPROST + TIMOLOL	
.NERVOUS SYSTEM.....	534, 535	.SENSORY ORGANS.....	613
<i>Lamotrigine Sandoz (SZ)</i>		<i>Latanoprost Actavis (GN)</i>	
.NERVOUS SYSTEM.....	534, 535	.SENSORY ORGANS.....	612
<i>Lamotrigine-GA (GN)</i>		<i>Latanoprost GH (GQ)</i>	
.NERVOUS SYSTEM.....	534, 535	.SENSORY ORGANS.....	612
<i>Lamotruster 100 (CR)</i>		<i>Latanoprost Pfizer (FZ)</i>	
.NERVOUS SYSTEM.....	534	.SENSORY ORGANS.....	612, 613
<i>Lamotruster 200 (CR)</i>		<i>Latanoprost Sandoz (SZ)</i>	
.NERVOUS SYSTEM.....	534	.SENSORY ORGANS.....	612, 613
<i>Lamotruster 25 (CR)</i>		<i>Latanoprost/Timolol Sandoz 50/5 (SZ)</i>	
.NERVOUS SYSTEM.....	534	.SENSORY ORGANS.....	613
<i>Lamotruster 50 (CR)</i>		<i>LaxaCon (GN)</i>	
.NERVOUS SYSTEM.....	535	.ALIMENTARY TRACT AND METABOLISM.....	75
<i>Lanoxin (QA)</i>		.Palliative Care.....	664, 665
.CARDIOVASCULAR SYSTEM	121	<i>lax-sachets (AE)</i>	

GENERIC/PROPRIETARY INDEX

.ALIMENTARY TRACT AND METABOLISM.....	75
.Palliative Care	664, 665
<i>Lax-Tab (AE)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	73
.Palliative Care	663
<i>Ledip (RA)</i>	
.CARDIOVASCULAR SYSTEM	133
LEFLUNOMIDE	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	315
<i>Leflunomide AN (EA)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	315, 316
<i>Leflunomide GH (GQ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	315, 316
<i>Leflunomide Sandoz (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	315, 316
<i>Leflunomide-GA (GN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	315, 316
<i>Lemtrada (GZ)</i>	
.Section 100	759, 1016
LENALIDOMIDE	
.Section 100	904, 905, 1162, 1164
<i>Lengout (LN)</i>	
.MUSCULO-SKELETAL SYSTEM	497
LENOGRASTIM	
.Section 100	761, 1018
<i>Lercadip (GN)</i>	
.CARDIOVASCULAR SYSTEM	133
<i>Lercan (QA)</i>	
.CARDIOVASCULAR SYSTEM	133
LERCANIDIPINE	
.CARDIOVASCULAR SYSTEM	133
LERCANIDIPINE + ENALAPRIL	
.CARDIOVASCULAR SYSTEM	142
<i>Lercanidipine GH (GQ)</i>	
.CARDIOVASCULAR SYSTEM	133
<i>Lercanidipine Sandoz (SZ)</i>	
.CARDIOVASCULAR SYSTEM	133
<i>Lescol (NV)</i>	
.CARDIOVASCULAR SYSTEM	159
<i>Lescol XL (NV)</i>	
.CARDIOVASCULAR SYSTEM	159
LETROZOLE	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	298
<i>Letrozole Actavis (VN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	298
<i>Letrozole AN (EA)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	298
<i>Letrozole FBM (FO)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	298
<i>Letrozole generichealth (GQ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	298
<i>Letrozole RBX (RA)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	298
<i>Letrozole Sandoz (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	298
<i>Letrozole-DRLA (RZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	298
<i>Letrozole-GA (GN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	298
<i>Leucovorin Calcium (Hospira Pty Limited) (HH)</i>	
.VARIOUS.....	627, 628
<i>Leucovorin Calcium (Pfizer Australia Pty Ltd) (PF)</i>	
.VARIOUS.....	628
<i>Leukeran (AS)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	256
<i>Leukoflex 1124 (BV)</i>	
.Repatriation Schedule	1287
<i>Leukoplast 01071-00 (BV)</i>	
.Repatriation Schedule	1286
<i>Leukoplast 01072-00 (BV)</i>	
.Repatriation Schedule	1286
<i>Leukoplast 01073-00 (BV)</i>	
.Repatriation Schedule	1286
<i>Leukopor 2471 (BV)</i>	
.Repatriation Schedule	1287
<i>Leukopor 2472 (BV)</i>	
.Repatriation Schedule	1287
<i>Leukopor 2474 (BV)</i>	
.Repatriation Schedule	1287
<i>Leukosilk 1021 (BV)</i>	
.Repatriation Schedule	1287
<i>Leukosilk 1022 (BV)</i>	
.Repatriation Schedule	1287
<i>Leukosilk 1024 (BV)</i>	
.Repatriation Schedule	1287
LEUPRORELIN	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	293
<i>Levactam (ER)</i>	
.NERVOUS SYSTEM.....	535, 536
<i>Levecetam 1000 (RZ)</i>	
.NERVOUS SYSTEM.....	535
<i>Levecetam 250 (RZ)</i>	
.NERVOUS SYSTEM.....	535
<i>Levecetam 500 (RZ)</i>	

GENERIC/PROPRIETARY INDEX

.NERVOUS SYSTEM.....	536	.VARIOUS.....	630, 631
<i>Levemir FlexPen (NF)</i>		LIGNOCAINE	
.ALIMENTARY TRACT AND METABOLISM.....	83	.CARDIOVASCULAR SYSTEM	121
<i>Levemir Penfill (NO)</i>		.Repatriation Schedule	1252
.ALIMENTARY TRACT AND METABOLISM.....	83	LINAGLIPTIN	
LEVETIRACETAM		.ALIMENTARY TRACT AND METABOLISM	94
.NERVOUS SYSTEM.....	535, 536	LINAGLIPTIN + METFORMIN	
<i>Levetiracetam AN (EA)</i>		.ALIMENTARY TRACT AND METABOLISM	86
.NERVOUS SYSTEM.....	535, 536	<i>Lincocin (PF)</i>	
<i>Levetiracetam generichealth (GQ)</i>		.ANTIINFECTIVES FOR SYSTEMIC USE	240
.NERVOUS SYSTEM.....	535, 536	LINCOMYCIN	
<i>Levetiracetam SZ (SZ)</i>		.ANTIINFECTIVES FOR SYSTEMIC USE	240
.NERVOUS SYSTEM.....	535, 536	<i>Link Medical Products Pty Ltd (LM)</i>	
<i>Levi 1000 (FM)</i>		.ANTIINFECTIVES FOR SYSTEMIC USE	249
.NERVOUS SYSTEM.....	535	.CARDIOVASCULAR SYSTEM	122
<i>Levi 250 (FM)</i>		.DERMATOLOGICALS	198
.NERVOUS SYSTEM.....	535	.Prescriber Bag	56
<i>Levi 500 (FM)</i>		.RESPIRATORY SYSTEM.....	602
.NERVOUS SYSTEM.....	536	<i>Lioresal 10 (NV)</i>	
<i>Levitacord (RA)</i>		.MUSCULO-SKELETAL SYSTEM	496
.NERVOUS SYSTEM.....	535, 536	<i>Lioresal 25 (NV)</i>	
<i>Levitam 1000 (QA)</i>		.MUSCULO-SKELETAL SYSTEM	496
.NERVOUS SYSTEM.....	535	<i>Lioresal Intrathecal (NV)</i>	
<i>Levitam 250 (QA)</i>		.Section 100.....	918, 1176
.NERVOUS SYSTEM.....	535	LIOTHYRONINE	
<i>Levitam 500 (QA)</i>		.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX	
.NERVOUS SYSTEM.....	536	HORMONES AND INSULINS	219
<i>Levitra (BN)</i>		<i>Lipex 10 (FR)</i>	
.Repatriation Schedule	1257	.CARDIOVASCULAR SYSTEM	166, 167
<i>Levlen ED (SY)</i>		<i>Lipex 20 (FR)</i>	
.GENITO URINARY SYSTEM AND SEX HORMONES .	202	.CARDIOVASCULAR SYSTEM	166, 168
LEVOCABASTINE		<i>Lipex 40 (FR)</i>	
.Repatriation Schedule	1267, 1269	.CARDIOVASCULAR SYSTEM	167, 168
LEVODOPA + BENSERAZIDE		<i>Lipex 80 (FR)</i>	
.NERVOUS SYSTEM.....	539	.CARDIOVASCULAR SYSTEM	167, 168
LEVODOPA + CARBIDOPA ANHYDROUS		<i>Lipidil (GO)</i>	
.NERVOUS SYSTEM.....	539	.CARDIOVASCULAR SYSTEM	169
.Section 100	920, 1178	<i>Lipigem (AF)</i>	
LEVODOPA + CARBIDOPA ANHYDROUS + ENTACAPONE		.CARDIOVASCULAR SYSTEM	169
.NERVOUS SYSTEM.....	540	<i>Lipistart (VF)</i>	
LEVONORGESTREL		.VARIOUS.....	648, 649
.GENITO URINARY SYSTEM AND SEX HORMONES 200,		<i>Lipitor (PF)</i>	
202		.CARDIOVASCULAR SYSTEM	156, 157, 158, 159
<i>Lexam 10 (QA)</i>		<i>Liposomal Doxorubicin SUN (ZF)</i>	
.NERVOUS SYSTEM.....	565	.Section 100.....	758, 1015
<i>Lexam 20 (QA)</i>		<i>Lipostat 10 (QA)</i>	
.NERVOUS SYSTEM.....	565	.CARDIOVASCULAR SYSTEM	159, 160
<i>Lexapro (LU)</i>		<i>Lipostat 20 (QA)</i>	
.NERVOUS SYSTEM.....	565, 566, 567	.CARDIOVASCULAR SYSTEM	159, 161
<i>Lexotan (RO)</i>		<i>Lipostat 40 (QA)</i>	
.Repatriation Schedule	1264	.CARDIOVASCULAR SYSTEM	160, 161
<i>Lezole (UA)</i>		<i>Lipostat 80 (QA)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING		.CARDIOVASCULAR SYSTEM	160, 161
AGENTS	298	<i>Liquifilm Tears (AG)</i>	
<i>Lifeline Attest (OI)</i>		.SENSORY ORGANS.....	623

GENERIC/PROPRIETARY INDEX

<i>Liquigen (SB)</i>		
.VARIOUS.....	632	
LISINAPRIL		
.CARDIOVASCULAR SYSTEM.....	136	
<i>Lisinopril AN (EA)</i>		
.CARDIOVASCULAR SYSTEM.....	136	
<i>Lisinopril generichealth (GQ)</i>		
.CARDIOVASCULAR SYSTEM.....	136	
<i>Lisinopril Sandoz (SZ)</i>		
.CARDIOVASCULAR SYSTEM.....	136	
<i>Lisinopril-DRLA (RZ)</i>		
.CARDIOVASCULAR SYSTEM.....	136	
<i>Lisinopril-GA (GN)</i>		
.CARDIOVASCULAR SYSTEM.....	136	
<i>Lithicarb (AS)</i>		
.NERVOUS SYSTEM.....	571	
LITHIUM CARBONATE		
.NERVOUS SYSTEM.....	571	
<i>Livostin (JT)</i>		
.Repatriation Schedule.....	1267, 1269	
<i>Locasol (SB)</i>		
.VARIOUS.....	650	
<i>Loceryl (GA)</i>		
.Repatriation Schedule.....	1250	
<i>Lodam SR 100 (ZP)</i>		
.NERVOUS SYSTEM.....	521	
<i>Lodam SR 150 (ZP)</i>		
.NERVOUS SYSTEM.....	521	
<i>Lofenoxal (IA)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	77	
<i>Logicin Rapid Relief (QA)</i>		
.Repatriation Schedule.....	1267	
<i>Logicin Sinus (QA)</i>		
.Repatriation Schedule.....	1267	
<i>Logynon ED (SY)</i>		
.GENITO URINARY SYSTEM AND SEX HORMONES .	202	
<i>Lomotil (IV)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	77	
<i>Loniten (PF)</i>		
.CARDIOVASCULAR SYSTEM.....	126	
LOPERAMIDE		
.ALIMENTARY TRACT AND METABOLISM.....	77	
<i>Lophlex (SB)</i>		
.VARIOUS.....	653	
LOPINAVIR + RITONAVIR		
.Section 100	753, 1010	
<i>Lopresor 100 (NV)</i>		
.CARDIOVASCULAR SYSTEM.....	130	
<i>Lopresor 50 (NV)</i>		
.CARDIOVASCULAR SYSTEM.....	130	
<i>Lorano (SZ)</i>		
.Repatriation Schedule.....	1268	
LORATADINE		
.Repatriation Schedule.....	1268	
<i>Lorstat 10 (AF)</i>		
.CARDIOVASCULAR SYSTEM.....	156, 158	
<i>Lorstat 20 (AF)</i>		
.CARDIOVASCULAR SYSTEM.....	157, 158	
<i>Lorstat 40 (AF)</i>		
.CARDIOVASCULAR SYSTEM.....	157, 158	
<i>Lorstat 80 (AF)</i>		
.CARDIOVASCULAR SYSTEM.....	157, 159	
LOSARTAN		
.CARDIOVASCULAR SYSTEM.....	146	
<i>Losec Tablets (AP)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	63, 64	
<i>Lovan (AL)</i>		
.NERVOUS SYSTEM.....	567	
<i>Lovan 20 Tab (AL)</i>		
.NERVOUS SYSTEM.....	567	
<i>Lovir (GN)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	250	
<i>LoxaLate (AF)</i>		
.NERVOUS SYSTEM.....	565	
<i>Loxip 500 (DO)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	242	
<i>Loxip 750 (DO)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	243	
LPV (IA)		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	227, 228	
LUBRICATING AGENT		
.Repatriation Schedule.....	1273	
<i>Lubri-Gel (PP)</i>		
.Repatriation Schedule.....	1273	
<i>Lucentis (NV)</i>		
.SENSORY ORGANS.....	617	
<i>Lucrin Depot 3 Month PDS (VE)</i>		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	293	
<i>Lucrin Depot 4 Month PDS (VE)</i>		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	293	
<i>Lucrin Depot 7.5mg PDS (VE)</i>		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	293	
<i>Lucrin Depot Paediatric 30 mg PDS (VE)</i>		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	293, 294	
<i>Lukair (FR)</i>		
.RESPIRATORY SYSTEM.....	603, 604	
<i>Lumigan (AG)</i>		
.SENSORY ORGANS.....	611	
<i>Lumigan PF (AG)</i>		
.SENSORY ORGANS.....	611	
<i>Lumin 10 (AF)</i>		
.NERVOUS SYSTEM.....	571	
<i>Lumin 20 (AF)</i>		
.NERVOUS SYSTEM.....	571	
<i>Lunava 10 (ZP)</i>		

GENERIC/PROPRIETARY INDEX

.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	315
<i>Lunava 20 (ZP)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	316
<i>Luvox (GO)</i>	
.NERVOUS SYSTEM.....	567, 568
<i>Lycinate (FM)</i>	
.CARDIOVASCULAR SYSTEM	123
<i>Lyclear (JT)</i>	
.ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS.....	593
<i>Lyrica (PF)</i>	
.NERVOUS SYSTEM.....	524

M

<i>Mabthera (RO)</i>	
.Section 100	917, 1175
MACITENTAN	
.Section 100	716, 971
<i>Macrodantin (PF)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	245
MACROGOL-3350	
.ALIMENTARY TRACT AND METABOLISM.....	74
.Palliative Care	663, 664
MACROGOL-3350 + SODIUM CHLORIDE + POTASSIUM CHLORIDE + BICARBONATE	
.ALIMENTARY TRACT AND METABOLISM.....	74
.Palliative Care	664
<i>Macrovic (QA)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	75
.Palliative Care	664, 665
<i>Madopar (RO)</i>	
.NERVOUS SYSTEM.....	539
<i>Madopar 125 (RO)</i>	
.NERVOUS SYSTEM.....	539
<i>Madopar 62.5 (RO)</i>	
.NERVOUS SYSTEM.....	539
<i>Madopar HBS (RO)</i>	
.NERVOUS SYSTEM.....	539
<i>Madopar Rapid 125 (RO)</i>	
.NERVOUS SYSTEM.....	539
<i>Madopar Rapid 62.5 (RO)</i>	
.NERVOUS SYSTEM.....	539
<i>Magicul 400 (AF)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	60
<i>Magmin (BB)</i>	
.Repatriation Schedule	1247
<i>MagMin (PBS) (BB)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	101
MAGNESIUM ASPARTATE DIHYDRATE	
.ALIMENTARY TRACT AND METABOLISM.....	101
.Repatriation Schedule	1246
<i>Mag-Sup (PP)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	101
.Repatriation Schedule	1247
<i>Malarone (GK)</i>	
.ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS	591
<i>Malean (FM)</i>	
.CARDIOVASCULAR SYSTEM	135
MANNITOL	
.Section 100.....	928, 1191
MARAVIROC	
.Section 100.....	754, 1012
<i>Marevan (FM)</i>	
.BLOOD AND BLOOD FORMING ORGANS.....	104
<i>MassBiologics tetanus and diphtheria toxoids adsorbed (CS)</i>	
.Prescriber Bag	56
<i>Max Pharma Ceftriaxone (GQ)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	236
<i>Maxalt (MK)</i>	
.NERVOUS SYSTEM.....	526
<i>Maxamox (SZ)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	225, 226
<i>Maxidex (AQ)</i>	
.SENSORY ORGANS.....	607
<i>Maxolon (IA)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	67, 68
.Prescriber Bag	57
<i>Maxor (AF)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	63, 64
<i>Mayne Pharma Aspirin (YT)</i>	
.BLOOD AND BLOOD FORMING ORGANS.....	106
<i>Mayne Pharma Doxycycline (YT)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	223, 224
<i>Mayne Pharma Erythromycin (YT)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	238
<i>MCT Oil (SB)</i>	
.VARIOUS.....	632
<i>MCT Pro-Cal (VF)</i>	
.VARIOUS.....	659
MEBENDAZOLE	
.Repatriation Schedule	1266
MEBEVERINE	
.Repatriation Schedule	1244
<i>Medipore 2961 (MM)</i>	
.Repatriation Schedule	1286
MEDROXYPROGESTERONE	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	291, 292
.GENITO URINARY SYSTEM AND SEX HORMONES	202, 208
MEFENAMIC ACID	
.MUSCULO-SKELETAL SYSTEM	494
<i>Mefix 310250 (MH)</i>	
.Repatriation Schedule	1286
<i>Megace (QA)</i>	

GENERIC/PROPRIETARY INDEX

.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	292	.Repatriation Schedule	1279
<i>Megafol 0.5 (AF)</i>		<i>Mepilex Border 295300 (MH)</i>	
.BLOOD AND BLOOD FORMING ORGANS	119	.Repatriation Schedule	1279
<i>Megafol 5 (AF)</i>		<i>Mepilex Border Ag (MH)</i>	
.BLOOD AND BLOOD FORMING ORGANS	119	.Repatriation Schedule	1279
MEGESTROL		<i>Mepilex Lite 284000 (MH)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	292	.Repatriation Schedule	1279
<i>Melizide (AF)</i>		<i>Mepilex Lite 284100 (MH)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	85	.Repatriation Schedule	1279
<i>Melolin 36361357 (SN)</i>		<i>Mepitac 298300 (MH)</i>	
.Repatriation Schedule	1285	.Repatriation Schedule	1287
<i>Melolin 66974933 (SN)</i>		<i>Mepitac 298400 (MH)</i>	
.Repatriation Schedule	1285	.Repatriation Schedule	1287
<i>Melox 15 (GN)</i>		<i>Mepitel 290510 (MH)</i>	
.MUSCULO-SKELETAL SYSTEM	491	.Repatriation Schedule	1285
<i>Melox 7.5 (GN)</i>		<i>Mepitel 290710 (MH)</i>	
.MUSCULO-SKELETAL SYSTEM	492	.Repatriation Schedule	1285
<i>Meloxiauro 15 (DO)</i>		<i>Meprazol (SZ)</i>	
.MUSCULO-SKELETAL SYSTEM	491	.ALIMENTARY TRACT AND METABOLISM.....	64
<i>Meloxiauro 7.5 (DO)</i>		MERCAPTOPYRINE	
.MUSCULO-SKELETAL SYSTEM	492	.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	258
<i>Meloxibell (GQ)</i>		MESALAZINE	
.MUSCULO-SKELETAL SYSTEM	491, 492	.ALIMENTARY TRACT AND METABOLISM.....	78, 79
MELOXICAM		<i>Mesasal (AS)</i>	
.MUSCULO-SKELETAL SYSTEM	491	.ALIMENTARY TRACT AND METABOLISM.....	79
<i>Meloxicam AN (EA)</i>		MESNA	
.MUSCULO-SKELETAL SYSTEM	491, 492	.VARIOUS.....	628
<i>Meloxicam Ranbaxy (RA)</i>		<i>Mestinon (IA)</i>	
.MUSCULO-SKELETAL SYSTEM	491, 492	.NERVOUS SYSTEM.....	584
<i>Meloxicam Sandoz (SZ)</i>		<i>Mestinon Timespan (IA)</i>	
.MUSCULO-SKELETAL SYSTEM	491, 492	.NERVOUS SYSTEM.....	584
<i>Meloxicam-GA (GN)</i>		MESTRANOL + NORETHISTERONE	
.MUSCULO-SKELETAL SYSTEM	491, 492	.GENITO URINARY SYSTEM AND SEX HORMONES .	202
MELPHALAN		<i>Metalyse (BY)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	256	.BLOOD AND BLOOD FORMING ORGANS.....	110
MEMANTINE		<i>Metamucil Natural Granular (PY)</i>	
.NERVOUS SYSTEM.....	582, 583	.Repatriation Schedule	1245
<i>Memantine generichealth (GQ)</i>		<i>Metamucil Orange Smooth (PY)</i>	
.NERVOUS SYSTEM.....	583	.Repatriation Schedule	1245
<i>Memantine RBX (RA)</i>		<i>Metatar (FM)</i>	
.NERVOUS SYSTEM.....	583	.CARDIOVASCULAR SYSTEM	130
<i>Memaxa (QA)</i>		<i>Metex XR (QA)</i>	
.NERVOUS SYSTEM.....	583	.ALIMENTARY TRACT AND METABOLISM.....	84
<i>Menopur 1200 (FP)</i>		METFORMIN	
.Section 100	1206	.ALIMENTARY TRACT AND METABOLISM.....	83
<i>Menopur 600 (FP)</i>		METFORMIN + GLIBENCLAMIDE	
.Section 100	1206	.ALIMENTARY TRACT AND METABOLISM.....	87
<i>Mepilex 294100 (MH)</i>		<i>Metformin 500 (CR)</i>	
.Repatriation Schedule	1279	.ALIMENTARY TRACT AND METABOLISM.....	83
<i>Mepilex Ag (MH)</i>		<i>Metformin 850 (CR)</i>	
.Repatriation Schedule	1279	.ALIMENTARY TRACT AND METABOLISM.....	84
<i>Mepilex Border 295200 (MH)</i>		<i>Metformin AN (EA)</i>	
		.ALIMENTARY TRACT AND METABOLISM.....	83, 84
		<i>Metformin generichealth (GQ)</i>	

GENERIC/PROPRIETARY INDEX

.ALIMENTARY TRACT AND METABOLISM.....	83, 84
<i>Metformin generichealth 1000 (GQ)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	83
<i>Metformin Ranbaxy (RA)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	83, 84
<i>Metformin Ranbaxy 1000 (RA)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	83
<i>Metformin Sandoz (SZ)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	83, 84
<i>Metformin-GA (GN)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	83, 84
<i>Methaccord (GN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	258
METHADONE	
.NERVOUS SYSTEM.....	519
.Palliative Care	673
.Section 100	1208
<i>Methoblastin (PF)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	258, 489
<i>Methopt (QA)</i>	
.SENSORY ORGANS.....	621
METHOTREXATE	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	258, 489
<i>Methotrexate MYX (YN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	258
METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA	
.Section 100	685, 940
METHYL SALICYLATE	
.Repatriation Schedule.....	1261
METHYL SALICYLATE + MENTHOL + EUCALYPTUS OIL	
.Repatriation Schedule.....	1261
METHYLDOPA	
.CARDIOVASCULAR SYSTEM	125
METHYLNALTREXONE	
.Palliative Care	666
METHYLPHENIDATE	
.NERVOUS SYSTEM.....	574, 575
<i>Methylpred (AL)</i>	
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX	
HORMONES AND INSULINS.....	217
METHYLPREDNISOLONE	
.DERMATOLOGICALS.....	196
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX	
HORMONES AND INSULINS.....	217
<i>Methylprednisolone Alphapharm (AF)</i>	
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX	
HORMONES AND INSULINS.....	217
METOCLOPRAMIDE	
.ALIMENTARY TRACT AND METABOLISM.....	67
<i>Metoclopramide Actavis (GN)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	67
<i>Metoclopramide AN (EA)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	67
<i>Metoprolol Actavis (GN)</i>	
.CARDIOVASCULAR SYSTEM	130
<i>Metoprolol AN (EA)</i>	
.CARDIOVASCULAR SYSTEM	130
<i>Metoprolol Sandoz (SZ)</i>	
.CARDIOVASCULAR SYSTEM	130
METOPROLOL SUCCINATE	
.CARDIOVASCULAR SYSTEM	129
METOPROLOL TARTRATE	
.CARDIOVASCULAR SYSTEM	130
<i>Metrogyl 200 (AF)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	244
<i>Metrogyl 400 (AF)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	244
<i>Metrol 100 (QA)</i>	
.CARDIOVASCULAR SYSTEM	130
<i>Metrol 50 (QA)</i>	
.CARDIOVASCULAR SYSTEM	130
<i>Metrol-XL 190 (QA)</i>	
.CARDIOVASCULAR SYSTEM	130
<i>Metrol-XL 23.75 (QA)</i>	
.CARDIOVASCULAR SYSTEM	130
<i>Metrol-XL 47.5 (QA)</i>	
.CARDIOVASCULAR SYSTEM	130
<i>Metrol-XL 95 (QA)</i>	
.CARDIOVASCULAR SYSTEM	130
METRONIDAZOLE	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	244, 245
<i>Metronidazole Sandoz IV (SZ)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	245
<i>Metronidazole-Clarix (AE)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	245
<i>Metronide 200 (AV)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	244
<i>Metronide 400 (AV)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	244
<i>Mezavant (ZI)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	78
<i>Miacalcic 100 (NV)</i>	
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX	
HORMONES AND INSULINS	221
MIANSERIN	
.NERVOUS SYSTEM.....	571
<i>Micardis (BY)</i>	
.CARDIOVASCULAR SYSTEM	146
<i>Micardis Plus 40/12.5 mg (BY)</i>	
.CARDIOVASCULAR SYSTEM	150
<i>Micardis Plus 80/12.5 mg (BY)</i>	
.CARDIOVASCULAR SYSTEM	150
<i>Micardis Plus 80/25 mg (BY)</i>	
.CARDIOVASCULAR SYSTEM	151
<i>Micolette (AE)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	75

GENERIC/PROPRIETARY INDEX

.Palliative Care	665	<i>Minirin Nasal Spray (FP)</i>	
.Repatriation Schedule	1245	.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX	
MICONAZOLE		HORMONES AND INSULINS	214, 215
.DERMATOLOGICALS	192	<i>Minitran 10 (IA)</i>	
.Repatriation Schedule	1250	.CARDIOVASCULAR SYSTEM	123
<i>Microgynon 30 ED (BN)</i>		<i>Minitran 15 (IA)</i>	
.GENITO URINARY SYSTEM AND SEX HORMONES .	202	.CARDIOVASCULAR SYSTEM	123
<i>Microgynon 50 ED (BN)</i>		<i>Minitran 5 (IA)</i>	
.GENITO URINARY SYSTEM AND SEX HORMONES .	202	.CARDIOVASCULAR SYSTEM	123
<i>Microlax (JT)</i>		MINOCYCLINE	
.ALIMENTARY TRACT AND METABOLISM	75	.ANTIINFECTIVES FOR SYSTEMIC USE	224
.Palliative Care	665, 666	<i>Minomycin-50 (QA)</i>	
.Repatriation Schedule	1245	.ANTIINFECTIVES FOR SYSTEMIC USE	224
<i>Microlut 28 (BN)</i>		MINOXIDIL	
.GENITO URINARY SYSTEM AND SEX HORMONES .	202	.CARDIOVASCULAR SYSTEM	125
<i>Micronelle 30 ED (TX)</i>		<i>Mircera (RO)</i>	
.GENITO URINARY SYSTEM AND SEX HORMONES .	202	.Section 100	685, 686, 941
<i>Micronor (JC)</i>		<i>Mirena (BN)</i>	
.GENITO URINARY SYSTEM AND SEX HORMONES .	202	.GENITO URINARY SYSTEM AND SEX HORMONES .	200
MIFEPRISTONE (&) MISOPROSTOL		MIRTAZAPINE	
.GENITO URINARY SYSTEM AND SEX HORMONES 200,		.NERVOUS SYSTEM	571
212		<i>Mirtazapine AN (EA)</i>	
<i>Milivin OD 15 (DO)</i>		.NERVOUS SYSTEM	572
.NERVOUS SYSTEM	571	<i>Mirtazapine AN ODT (EA)</i>	
<i>Milivin OD 30 (DO)</i>		.NERVOUS SYSTEM	571
.NERVOUS SYSTEM	571	<i>Mirtazapine GH (GQ)</i>	
<i>Milivin OD 45 (DO)</i>		.NERVOUS SYSTEM	572
.NERVOUS SYSTEM	571	<i>Mirtazapine Sandoz (SZ)</i>	
MILK POWDER LACTOSE FREE FORMULA		.NERVOUS SYSTEM	572
.VARIOUS	649	<i>Mirtazapine Sandoz ODT 15 (SZ)</i>	
MILK POWDER LACTOSE FREE FORMULA PREDIGESTED		.NERVOUS SYSTEM	571
.VARIOUS	649	<i>Mirtazapine Sandoz ODT 30 (SZ)</i>	
MILK POWDER LACTOSE MODIFIED PREDIGESTED		.NERVOUS SYSTEM	571
.VARIOUS	650	<i>Mirtazapine Sandoz ODT 45 (SZ)</i>	
MILK POWDER SYNTHETIC LOW CALCIUM		.NERVOUS SYSTEM	571
.VARIOUS	650	<i>Mirtazapine-GA (GN)</i>	
MILK PROTEIN AND FAT FORMULA WITH VITAMINS AND		.NERVOUS SYSTEM	572
MINERALS CARBOHYDRATE FREE		<i>Mirtazon (QA)</i>	
.VARIOUS	658	.NERVOUS SYSTEM	572
<i>Minax 100 (AF)</i>		<i>Mistrom (ER)</i>	
.CARDIOVASCULAR SYSTEM	130	.CARDIOVASCULAR SYSTEM	130
<i>Minax 50 (AF)</i>		<i>Mixtard 30/70 InnoLet (NI)</i>	
.CARDIOVASCULAR SYSTEM	130	.ALIMENTARY TRACT AND METABOLISM	82
<i>Minax XL (AF)</i>		<i>Mixtard 30/70 Penfill 3 mL (NO)</i>	
.CARDIOVASCULAR SYSTEM	130	.ALIMENTARY TRACT AND METABOLISM	82
<i>Minidiab (PF)</i>		<i>Mixtard 50/50 Penfill 3 mL (NO)</i>	
.ALIMENTARY TRACT AND METABOLISM	85	.ALIMENTARY TRACT AND METABOLISM	82
<i>Minipress (PF)</i>		<i>Mizart (AF)</i>	
.CARDIOVASCULAR SYSTEM	125	.CARDIOVASCULAR SYSTEM	146
<i>Minirin (FP)</i>		<i>Mizart HCT 40/12.5 mg (AF)</i>	
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX		.CARDIOVASCULAR SYSTEM	150
HORMONES AND INSULINS	214, 215	<i>Mizart HCT 80/12.5 mg (AF)</i>	
<i>Minirin Melt (FP)</i>		.CARDIOVASCULAR SYSTEM	150
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX		<i>Mizart HCT 80/25 mg (AF)</i>	
HORMONES AND INSULINS	214	.CARDIOVASCULAR SYSTEM	151

GENERIC/PROPRIETARY INDEX

<i>MMA/PA Anamix infant (SB)</i>		
.VARIOUS.....	652	
<i>MMA/PA cooler 15 (VF)</i>		
.VARIOUS.....	652	
<i>MMA/PA express 15 (VF)</i>		
.VARIOUS.....	652	
<i>MMA/PA gel (VF)</i>		
.VARIOUS.....	652	
<i>Mobic (BY)</i>		
.MUSCULO-SKELETAL SYSTEM	491, 492	
<i>Mobilis 10 (AF)</i>		
.MUSCULO-SKELETAL SYSTEM	492	
<i>Mobilis 20 (AF)</i>		
.MUSCULO-SKELETAL SYSTEM	492, 493	
<i>Mobilis D-10 (AF)</i>		
.MUSCULO-SKELETAL SYSTEM	492	
<i>Mobilis D-20 (AF)</i>		
.MUSCULO-SKELETAL SYSTEM	493	
<i>MOCLOBEMIDE</i>		
.NERVOUS SYSTEM.....	569	
<i>Moclobemide AN (EA)</i>		
.NERVOUS SYSTEM.....	569, 570	
<i>Moclobemide Sandoz (SZ)</i>		
.NERVOUS SYSTEM.....	569, 570	
<i>MODAFINIL</i>		
.NERVOUS SYSTEM.....	575	
<i>Modavigil (CS)</i>		
.NERVOUS SYSTEM.....	576	
<i>Modecate (BQ)</i>		
.NERVOUS SYSTEM.....	544	
<i>Moduretic (AS)</i>		
.CARDIOVASCULAR SYSTEM	127	
<i>Mogadon (IA)</i>		
.NERVOUS SYSTEM.....	529, 561, 562	
.Palliative Care	675, 676	
<i>Mohexal (HX)</i>		
.NERVOUS SYSTEM.....	569	
<i>Molaxole (HM)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	75	
.Palliative Care	664, 665	
<i>Momasone (QA)</i>		
.DERMATOLOGICALS.....	196	
<i>MOMETASONE</i>		
.DERMATOLOGICALS.....	196	
.Repatriation Schedule.....	1253	
<i>Momex SR 10 (QA)</i>		
.NERVOUS SYSTEM.....	513	
<i>Momex SR 100 (QA)</i>		
.NERVOUS SYSTEM.....	513	
<i>Momex SR 30 (QA)</i>		
.NERVOUS SYSTEM.....	513	
<i>Momex SR 60 (QA)</i>		
.NERVOUS SYSTEM.....	513	
<i>Monace 10 (AF)</i>		
.CARDIOVASCULAR SYSTEM	136	
<i>Monace 20 (AF)</i>		
.CARDIOVASCULAR SYSTEM	136	
<i>Monodur 120 mg (PM)</i>		
.CARDIOVASCULAR SYSTEM	123	
<i>Monodur 60 mg (PM)</i>		
.CARDIOVASCULAR SYSTEM	124	
<i>Monofeme 28 (FZ)</i>		
.GENITO URINARY SYSTEM AND SEX HORMONES	201	
<i>Monogen (SB)</i>		
.VARIOUS.....	648, 649	
<i>Monoplus 10/12.5 (BQ)</i>		
.CARDIOVASCULAR SYSTEM	141	
<i>Monoplus 20/12.5 (BQ)</i>		
.CARDIOVASCULAR SYSTEM	141	
<i>Monopril (BQ)</i>		
.CARDIOVASCULAR SYSTEM	136	
<i>Montair 4 (GN)</i>		
.RESPIRATORY SYSTEM.....	603	
<i>Montair 5 (GN)</i>		
.RESPIRATORY SYSTEM.....	604	
<i>MONTELUKAST</i>		
.RESPIRATORY SYSTEM.....	603	
<i>Montelukast AN (EA)</i>		
.RESPIRATORY SYSTEM.....	603, 604	
<i>Montelukast GH (GQ)</i>		
.RESPIRATORY SYSTEM.....	603, 604	
<i>Montelukast RBX (RA)</i>		
.RESPIRATORY SYSTEM.....	603, 604	
<i>Montelukast Sandoz 4 (SZ)</i>		
.RESPIRATORY SYSTEM.....	603	
<i>Montelukast Sandoz 5 (SZ)</i>		
.RESPIRATORY SYSTEM.....	604	
<i>MORPHINE</i>		
.NERVOUS SYSTEM.....	512, 513, 514	
.Palliative Care.....	671	
.Repatriation Schedule	1263	
<i>MORPHINE MR APOTEX (TX)</i>		
.NERVOUS SYSTEM.....	513	
<i>Motilium (JC)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	67	
<i>Movalis 15 (QA)</i>		
.MUSCULO-SKELETAL SYSTEM	491	
<i>Movalis 7.5 (QA)</i>		
.MUSCULO-SKELETAL SYSTEM	492	
<i>Movicol (NE)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	75	
.Palliative Care.....	664, 665	
<i>Movicol Liquid (NE)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	75	
.Palliative Care.....	664, 665	
<i>Movox 100 (AF)</i>		
.NERVOUS SYSTEM.....	567	
<i>Movox 50 (AL)</i>		
.NERVOUS SYSTEM.....	567	
<i>Moxicam 15 (AF)</i>		

GENERIC/PROPRIETARY INDEX

.MUSCULO-SKELETAL SYSTEM	491
<i>Moxicam 7.5 (AF)</i>	
.MUSCULO-SKELETAL SYSTEM	492
<i>Moxiclav Duo 500/125 (QA)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	229, 230
<i>Moxiclav Duo Forte 875/125 (QA)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	230
MOXONIDINE	
.CARDIOVASCULAR SYSTEM	125
<i>Mozobil (GZ)</i>	
.Section 100	780, 1038
<i>MS Contin (MF)</i>	
.NERVOUS SYSTEM.....	513, 514
.Palliative Care	671
.Repatriation Schedule.....	1263
<i>MS Contin Suspension 100 mg (MF)</i>	
.NERVOUS SYSTEM.....	513
<i>MS Contin Suspension 20 mg (MF)</i>	
.NERVOUS SYSTEM.....	513
<i>MS Contin Suspension 200 mg (MF)</i>	
.NERVOUS SYSTEM.....	514
<i>MS Contin Suspension 30 mg (MF)</i>	
.NERVOUS SYSTEM.....	512
<i>MS Contin Suspension 60 mg (MF)</i>	
.NERVOUS SYSTEM.....	513
<i>MS Mono (MF)</i>	
.NERVOUS SYSTEM.....	513
<i>MS-2 Step (XH)</i>	
.GENITO URINARY SYSTEM AND SEX HORMONES	200, 212
<i>MSUD AID III (SB)</i>	
.VARIOUS.....	655
<i>MSUD amino5 (VF)</i>	
.VARIOUS.....	651
<i>MSUD Anamix infant (SB)</i>	
.VARIOUS.....	655
<i>MSUD Anamix Junior (SB)</i>	
.VARIOUS.....	655
<i>MSUD Anamix Junior LQ (SB)</i>	
.VARIOUS.....	655
<i>MSUD cooler 10 (VF)</i>	
.VARIOUS.....	654
<i>MSUD cooler 15 (VF)</i>	
.VARIOUS.....	654
<i>MSUD cooler 20 (VF)</i>	
.VARIOUS.....	654
<i>MSUD express 15 (VF)</i>	
.VARIOUS.....	654
<i>MSUD express 20 (VF)</i>	
.VARIOUS.....	654
<i>MSUD gel (VF)</i>	
.VARIOUS.....	654
<i>MSUD Lophlex LQ 20 (SB)</i>	
.VARIOUS.....	654
<i>MSUD Maxamaid (SB)</i>	

.VARIOUS.....	655
<i>MSUD Maxamum (SB)</i>	
.VARIOUS.....	655
MUIPROCIN	
.Repatriation Schedule	1252
.RESPIRATORY SYSTEM.....	594
<i>Murelax (FM)</i>	
.NERVOUS SYSTEM.....	561
.Palliative Care.....	675
<i>Mycobutin (PF)</i>	
.Section 100.....	737, 993
MYCOPHENOLATE	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	316
.Section 100.....	802, 1060, 1061
<i>Mycophenolate Sandoz (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	316
.Section 100.....	802, 803, 1061
<i>Mycostatin (FM)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	60
.DERMATOLOGICALS	192
.Repatriation Schedule	1250
<i>Myfortic (NV)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	316
.Section 100.....	802, 1060
<i>MyGlucoHealth (EH)</i>	
.VARIOUS.....	630, 631
<i>Mylanta Double Strength (JT)</i>	
.Repatriation Schedule	1244
<i>Mylanta P (JT)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	60
<i>Myleran (AS)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	256
<i>Myocrisin (SW)</i>	
.MUSCULO-SKELETAL SYSTEM	496
<i>Mysoline (LM)</i>	
.NERVOUS SYSTEM.....	528

N

NAFARELIN	
.Section 100.....	1206
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX	
HORMONES AND INSULINS	215
NALOXONE	
.VARIOUS.....	626
<i>Naloxone minijet (UC)</i>	
.Prescriber Bag	57
.VARIOUS.....	626
NALTREXONE	
.NERVOUS SYSTEM.....	588
<i>Naltrexone GH (GQ)</i>	

GENERIC/PROPRIETARY INDEX

.NERVOUS SYSTEM.....	588	.ANTINEOPLASTIC AND IMMUNOMODULATING	
NANDROLONE DECANOATE		AGENTS	488
.ALIMENTARY TRACT AND METABOLISM.....	101	.Section 100.....	903, 1161
NAPHAZOLINE		<i>Neoral 10 (NV)</i>	
.Repatriation Schedule.....	1269	.ANTINEOPLASTIC AND IMMUNOMODULATING	
NAPHAZOLINE + ANTAZOLINE		AGENTS	488
.Repatriation Schedule.....	1269	.Section 100.....	903, 1161
<i>Naprosyn (RO)</i>		<i>Neoral 100 (NV)</i>	
.MUSCULO-SKELETAL SYSTEM	493, 494	.ANTINEOPLASTIC AND IMMUNOMODULATING	
.Palliative Care	669	AGENTS	488
<i>Naprosyn SR1000 (RO)</i>		.Section 100.....	903, 1161
.MUSCULO-SKELETAL SYSTEM	493	<i>Neoral 25 (NV)</i>	
.Palliative Care	669	.ANTINEOPLASTIC AND IMMUNOMODULATING	
<i>Naprosyn SR750 (RO)</i>		AGENTS	488
.MUSCULO-SKELETAL SYSTEM	494	.Section 100.....	903, 1161
.Palliative Care	669	<i>Neoral 50 (NV)</i>	
NAPROXEN		.ANTINEOPLASTIC AND IMMUNOMODULATING	
.MUSCULO-SKELETAL SYSTEM	493, 494	AGENTS	488
.Palliative Care	669, 670	.Section 100.....	903, 1161
<i>Naramig (AS)</i>		<i>NeoRecormon (RO)</i>	
.NERVOUS SYSTEM.....	525	.Section 100.....	685, 940
NARATRIPTAN		<i>Neotigason (UA)</i>	
.NERVOUS SYSTEM.....	525	.DERMATOLOGICALS	194
<i>Nardil (LM)</i>		<i>Nesina (TK)</i>	
.NERVOUS SYSTEM.....	569	.ALIMENTARY TRACT AND METABOLISM.....	94
NATALIZUMAB		<i>Nesina Met 12.5/1000 (TK)</i>	
.Section 100	803, 1061	.ALIMENTARY TRACT AND METABOLISM.....	86
<i>Natrilix (SE)</i>		<i>Nesina Met 12.5/500 (TK)</i>	
.CARDIOVASCULAR SYSTEM	126	.ALIMENTARY TRACT AND METABOLISM.....	86
<i>Natrilix SR (SE)</i>		<i>Nesina Met 12.5/850 (TK)</i>	
.CARDIOVASCULAR SYSTEM	126	.ALIMENTARY TRACT AND METABOLISM.....	86
<i>Navelbine (FB)</i>		<i>Neulactil (SW)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING		.NERVOUS SYSTEM.....	544
AGENTS	259	<i>Neulasta (AN)</i>	
<i>Nebilet (FK)</i>		.Section 100.....	762, 1020
.CARDIOVASCULAR SYSTEM	130, 131	<i>Neupogen (AN)</i>	
NEBIVOLOL		.Section 100.....	761, 1018
.CARDIOVASCULAR SYSTEM	130	<i>Neupro (UC)</i>	
NEDOCROMIL		.NERVOUS SYSTEM.....	543
.RESPIRATORY SYSTEM	602	<i>Neurontin (PF)</i>	
<i>Neo-B12 (HH)</i>		.NERVOUS SYSTEM.....	531, 532
.BLOOD AND BLOOD FORMING ORGANS	119	.Repatriation Schedule	1263, 1264
<i>Neocate Advance (SB)</i>		<i>Nevipin (GN)</i>	
.VARIOUS.....	634, 636	.Section 100.....	750, 1007
<i>Neocate Advance Vanilla (SB)</i>		NEVIRAPINE	
.VARIOUS.....	634, 636	.Section 100.....	750, 1007
<i>Neocate Gold (SB)</i>		<i>Nevirapine Alphapharm (AF)</i>	
.VARIOUS.....	640, 643, 644	.Section 100.....	750, 1007
<i>Neocate LCP (SB)</i>		<i>Nevirapine RBX (RA)</i>	
.VARIOUS.....	638, 639	.Section 100.....	750, 1007
<i>Neo-Mercazole (LM)</i>		<i>Nexavar (BN)</i>	
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX		.ANTINEOPLASTIC AND IMMUNOMODULATING	
HORMONES AND INSULINS.....	220	AGENTS	287, 288
<i>Neoral (NV)</i>		<i>Nexcare Durable Cloth First Aid Tape 799 (MM)</i>	
		.Repatriation Schedule	1287

GENERIC/PROPRIETARY INDEX

<i>Nexcare Gentle Paper First Aid Tape 789 (MM)</i>		<i>Nitrolingual Pumpspray (SW)</i>	
.Repatriation Schedule	1287	.CARDIOVASCULAR SYSTEM	123
<i>Nexcare Tegaderm Transparent H1624 (MM)</i>		.Prescriber Bag	56
.Repatriation Schedule	1278	<i>Nivestim (HH)</i>	
<i>Nexcare Tegaderm Transparent H1626 (MM)</i>		.Section 100	760, 761, 1018
.Repatriation Schedule	1278	<i>Nizac (LN)</i>	
<i>Nexium (AP)</i>		.ALIMENTARY TRACT AND METABOLISM	61
.ALIMENTARY TRACT AND METABOLISM	62	NIZATIDINE	
<i>Nexium Hp7 (AP)</i>		.ALIMENTARY TRACT AND METABOLISM	61
.ALIMENTARY TRACT AND METABOLISM	67	<i>Nizoral 1% (JT)</i>	
<i>Nicabate CQ 14 (GC)</i>		.DERMATOLOGICALS	192
.Repatriation Schedule	1265	<i>Nizoral 2% (JT)</i>	
<i>Nicabate CQ 21 (GC)</i>		.DERMATOLOGICALS	192
.Repatriation Schedule	1265	.Repatriation Schedule	1250
<i>Nicabate P (GC)</i>		<i>Nizoral 2% Cream (JT)</i>	
.NERVOUS SYSTEM	586	.DERMATOLOGICALS	192
NICORANDIL		<i>Nolvadex-D (AP)</i>	
.CARDIOVASCULAR SYSTEM	124	.ANTINEOPLASTIC AND IMMUNOMODULATING	
<i>nicorette 16hr Invisipatch (JT)</i>		AGENTS	294
.NERVOUS SYSTEM	586	<i>Nordette 28 (PF)</i>	
<i>Nicorette Patch (JT)</i>		.GENITO URINARY SYSTEM AND SEX HORMONES .	202
.Repatriation Schedule	1265	<i>Nordip (AF)</i>	
NICOTINE		.CARDIOVASCULAR SYSTEM	132
.NERVOUS SYSTEM	584, 585, 586	<i>Norditropin FlexPro (NO)</i>	
.Repatriation Schedule	1265	.Section 100	1204
<i>Nicotinell Step 1 (NC)</i>		<i>Norditropin SimpleXx (NO)</i>	
.NERVOUS SYSTEM	585, 586	.Section 100	1203, 1204
<i>Nicotinell Step 2 (NC)</i>		NORETHISTERONE	
.NERVOUS SYSTEM	585	.GENITO URINARY SYSTEM AND SEX HORMONES	202,
<i>Nicotinell Step 3 (NC)</i>		208	
.NERVOUS SYSTEM	585	NORETHISTERONE ACETATE + OESTRADIOL	
<i>Nidem (QA)</i>		.GENITO URINARY SYSTEM AND SEX HORMONES .	208
.ALIMENTARY TRACT AND METABOLISM	84	NORETHISTERONE ACETATE + OESTRADIOL (&)	
NIFEDIPINE		OESTRADIOL	
.CARDIOVASCULAR SYSTEM	133	.GENITO URINARY SYSTEM AND SEX HORMONES .	208
NILOTINIB		NORFLOXACIN	
.ANTINEOPLASTIC AND IMMUNOMODULATING		.ANTIINFECTIVES FOR SYSTEMIC USE	243
AGENTS	280, 281	<i>Norfloxacin AN (EA)</i>	
<i>Nilstat (QA)</i>		.ANTIINFECTIVES FOR SYSTEMIC USE	243
.ALIMENTARY TRACT AND METABOLISM	60, 76	<i>Norfloxacin Sandoz (SZ)</i>	
.Repatriation Schedule	1256	.ANTIINFECTIVES FOR SYSTEMIC USE	243
NILUTAMIDE		<i>Norfloxacin-GA (GN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING		.ANTIINFECTIVES FOR SYSTEMIC USE	243
AGENTS	296	<i>Noriday 28 Day (PF)</i>	
NITRAZEPAM		.GENITO URINARY SYSTEM AND SEX HORMONES .	202
.NERVOUS SYSTEM	529, 561, 562	<i>Norimin 28 Day (FZ)</i>	
.Palliative Care	675	.GENITO URINARY SYSTEM AND SEX HORMONES .	202
<i>Nitro-Dur 10 (MK)</i>		<i>Norimin-1 28 Day (FZ)</i>	
.CARDIOVASCULAR SYSTEM	123	.GENITO URINARY SYSTEM AND SEX HORMONES .	202
<i>Nitro-Dur 15 (MK)</i>		<i>Norinyl-1/28 (PF)</i>	
.CARDIOVASCULAR SYSTEM	123	.GENITO URINARY SYSTEM AND SEX HORMONES .	202
<i>Nitro-Dur 5 (MK)</i>		<i>Normacol Plus (NE)</i>	
.CARDIOVASCULAR SYSTEM	123	.ALIMENTARY TRACT AND METABOLISM	73
NITROFURANTOIN		.Palliative Care	663
.ANTIINFECTIVES FOR SYSTEMIC USE	245	.Repatriation Schedule	1245

GENERIC/PROPRIETARY INDEX

<i>Normison (QA)</i>		<i>Nupentin 400 (AF)</i>	
.NERVOUS SYSTEM.....	562	.NERVOUS SYSTEM.....	532
.Palliative Care	676	.Repatriation Schedule	1264
<i>Norprolac (FP)</i>		<i>Nupentin Tabs (AF)</i>	
.GENITO URINARY SYSTEM AND SEX HORMONES .	201	.NERVOUS SYSTEM.....	532
<i>Norspan (MF)</i>		.Repatriation Schedule	1264
.NERVOUS SYSTEM.....	520	<i>NutropinAq (IS)</i>	
NORTRIPTYLINE		.Section 100.....	1204
.NERVOUS SYSTEM.....	564	<i>Nyogel (AS)</i>	
<i>Norvapine (GN)</i>		.SENSORY ORGANS.....	611
.CARDIOVASCULAR SYSTEM	132	NYSTATIN	
<i>Norvasc (PF)</i>		.ALIMENTARY TRACT AND METABOLISM.....	60, 76
.CARDIOVASCULAR SYSTEM	132	.DERMATOLOGICALS	192
<i>Norvir (VE)</i>		.Repatriation Schedule	1250, 1256
.Section 100	741, 997		
<i>Noten (AF)</i>			
.CARDIOVASCULAR SYSTEM	128		
<i>Novasone (FR)</i>			
.DERMATOLOGICALS.....	196, 197		
<i>Novatin (TX)</i>			
.DERMATOLOGICALS.....	194		
<i>Novicrit (SZ)</i>			
.Section 100	685, 940		
<i>NovoMix 30 FlexPen (NF)</i>			
.ALIMENTARY TRACT AND METABOLISM.....	82		
<i>NovoMix 30 Penfill 3 mL (NO)</i>			
.ALIMENTARY TRACT AND METABOLISM.....	82		
<i>NovoRapid (NO)</i>			
.ALIMENTARY TRACT AND METABOLISM.....	81		
<i>NovoRapid FlexPen (NF)</i>			
.ALIMENTARY TRACT AND METABOLISM.....	81		
<i>NovoRapid Penfill 3 mL (NO)</i>			
.ALIMENTARY TRACT AND METABOLISM.....	81		
<i>Noxafil (MK)</i>			
.ANTIINFECTIVES FOR SYSTEMIC USE.....	247		
<i>Nplate (AN)</i>			
.Section 100	684, 939		
<i>Nuelin (IA)</i>			
.RESPIRATORY SYSTEM	603		
<i>Nuelin-SR 200 (IA)</i>			
.RESPIRATORY SYSTEM	603		
<i>Nuelin-SR 250 (IA)</i>			
.RESPIRATORY SYSTEM	603		
<i>Nuelin-SR 300 (IA)</i>			
.RESPIRATORY SYSTEM	603		
<i>Nufloxib (AF)</i>			
.ANTIINFECTIVES FOR SYSTEMIC USE.....	243		
<i>Nu-Gel 2497 (KI)</i>			
.Repatriation Schedule	1285		
<i>Nupentin 100 (AF)</i>			
.NERVOUS SYSTEM.....	531		
.Repatriation Schedule	1263		
<i>Nupentin 300 (AF)</i>			
.NERVOUS SYSTEM.....	531		
.Repatriation Schedule	1263		

O

O.R.S. (AS)	
.ALIMENTARY TRACT AND METABOLISM.....	77
OCTREOTIDE	
.Section 100.....	735, 990
<i>Octreotide (SUN) (ZF)</i>	
.Section 100.....	736, 991
<i>Octreotide MaxRx (GQ)</i>	
.Section 100.....	736, 991
<i>Ocufen (AG)</i>	
.SENSORY ORGANS.....	608
<i>Ocuflox (AG)</i>	
.SENSORY ORGANS.....	606, 607
<i>Odaplix SR (AF)</i>	
.CARDIOVASCULAR SYSTEM	126
OESTRADIOL	
.GENITO URINARY SYSTEM AND SEX HORMONES .	207
OESTRADIOL (&) OESTRADIOL + DYDROGESTERONE	
.GENITO URINARY SYSTEM AND SEX HORMONES .	209
OESTRADIOL + DYDROGESTERONE	
.GENITO URINARY SYSTEM AND SEX HORMONES .	208
OESTRIOL	
.GENITO URINARY SYSTEM AND SEX HORMONES .	207
OFLOXACIN	
.SENSORY ORGANS.....	606
OLANZAPINE	
.NERVOUS SYSTEM.....	546, 547, 548, 549, 550, 551
<i>Olanzapine AN (EA)</i>	
.NERVOUS SYSTEM.....	547, 549, 550, 551
<i>Olanzapine AN ODT (EA)</i>	
.NERVOUS SYSTEM.....	546, 548, 549
<i>Olanzapine generichealth 10 (GQ)</i>	
.NERVOUS SYSTEM.....	547
<i>Olanzapine generichealth 2.5 (GQ)</i>	
.NERVOUS SYSTEM.....	548
<i>Olanzapine generichealth 5 (GQ)</i>	
.NERVOUS SYSTEM.....	550
<i>Olanzapine generichealth 7.5 (GQ)</i>	
.NERVOUS SYSTEM.....	551

GENERIC/PROPRIETARY INDEX

<i>Olanzapine GH (GQ)</i>	
.NERVOUS SYSTEM.....	547, 550, 551
<i>Olanzapine ODT generichealth 10 (GQ)</i>	
.NERVOUS SYSTEM.....	546
<i>Olanzapine ODT generichealth 5 (GQ)</i>	
.NERVOUS SYSTEM.....	546
<i>Olanzapine ODT-DRLA (RZ)</i>	
.NERVOUS SYSTEM.....	546
<i>Olanzapine RBX (RA)</i>	
.NERVOUS SYSTEM.....	547, 549, 550, 551
<i>Olanzapine RBX ODT (RA)</i>	
.NERVOUS SYSTEM.....	546
<i>Olanzapine Sandoz (SZ)</i>	
.NERVOUS SYSTEM.....	547, 549, 550, 551
<i>Olanzapine Sandoz ODT 10 (SZ)</i>	
.NERVOUS SYSTEM.....	546
<i>Olanzapine Sandoz ODT 5 (SZ)</i>	
.NERVOUS SYSTEM.....	546
<i>Olanzapine-DRLA (RZ)</i>	
.NERVOUS SYSTEM.....	547, 549, 550, 551
<i>Olanzapine-GA (GN)</i>	
.NERVOUS SYSTEM.....	547, 549, 550, 551
<i>Olanzapine-GA ODT (GN)</i>	
.NERVOUS SYSTEM.....	546
OLMESARTAN + AMLODIPINE + HYDROCHLOROTHIAZIDE	
.CARDIOVASCULAR SYSTEM.....	153
OLMESARTAN MEDOXOMIL	
.CARDIOVASCULAR SYSTEM.....	146
OLMESARTAN MEDOXOMIL + AMLODIPINE	
.CARDIOVASCULAR SYSTEM.....	152
OLMESARTAN MEDOXOMIL + HYDROCHLOROTHIAZIDE	
.CARDIOVASCULAR SYSTEM.....	150
<i>Olmotec (MK)</i>	
.CARDIOVASCULAR SYSTEM.....	146
<i>Olmotec Plus (MK)</i>	
.CARDIOVASCULAR SYSTEM.....	150
OLSALAZINE	
.ALIMENTARY TRACT AND METABOLISM.....	80
<i>Olysio (JC)</i>	
.Section 100.....	743, 999
OMALIZUMAB	
.Section 100.....	922, 1180, 1184
<i>Omegapharm Pty Ltd (OE)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	237
<i>Omepral (TX)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	64
OMEPRAZOLE	
.ALIMENTARY TRACT AND METABOLISM.....	63, 64
<i>Omeprazole AN (EA)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	64
<i>Omeprazole generichealth (GQ)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	64
<i>Omeprazole RBX (RA)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	64
<i>Omeprazole Sandoz (HX)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	63, 64
<i>Omeprazole Sandoz (SZ)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	64
<i>Omeprazole-GA (GN)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	64
<i>Omepro-GA (GN)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	63, 64
<i>Omnitrope (SZ)</i>	
.Section 100.....	1203
<i>Onbrez (NV)</i>	
.RESPIRATORY SYSTEM.....	594
<i>OncoTICE (MK)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS.....	303
ONDANSETRON	
.ALIMENTARY TRACT AND METABOLISM.....	68, 69, 70
<i>Ondansetron Alphapharm (AF)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	70
<i>Ondansetron AN (EA)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	69, 70
<i>Ondansetron AN ODT (EA)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	68, 69
<i>Ondansetron Kabi (PK)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	70
<i>Ondansetron ODT-DRLA (RZ)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	69
<i>Ondansetron-Clarix (AE)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	70
<i>Ondansetron-DRLA (RZ)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	69, 70
<i>Ondaz (SZ)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	69, 70
<i>Ondaz Zydix (SZ)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	69
<i>OneTouch Select (JJ)</i>	
.VARIOUS.....	630, 631
<i>OneTouch Verio (JJ)</i>	
.VARIOUS.....	630, 631
<i>Onglyza (AP)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	95
<i>Onsetron (ZP)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	70
<i>Onsetron 4 (ZP)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	70
<i>Onsetron 8 (ZP)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	70
<i>Onsetron ODT 4 (GN)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	69
<i>Onsetron ODT 8 (GN)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	69
<i>Op-Site Flexigrid 4629 (SN)</i>	
.Repatriation Schedule.....	1277
<i>Opsumit (AT)</i>	
.Section 100.....	721, 976
<i>Opticrom (SW)</i>	

GENERIC/PROPRIETARY INDEX

.SENSORY ORGANS.....	614	<i>Otodex (AV)</i>	
<i>Optifresh eye gel (PP)</i>		.SENSORY ORGANS.....	624
.SENSORY ORGANS.....	619	<i>Ovestin (AS)</i>	
<i>Optifresh Plus (PP)</i>		.GENITO URINARY SYSTEM AND SEX HORMONES .	207
.SENSORY ORGANS.....	619	<i>Ovestin Ovula (AS)</i>	
<i>Optifresh Tears (PP)</i>		.GENITO URINARY SYSTEM AND SEX HORMONES .	207
.SENSORY ORGANS.....	619, 620	<i>Ovidrel (SG)</i>	
<i>Optium Omega (MS)</i>		.Section 100.....	1205
.VARIOUS.....	630, 631	OXAZEPAM	
<i>Optive (AG)</i>		.NERVOUS SYSTEM.....	561
.SENSORY ORGANS.....	620	.Palliative Care.....	675
<i>Orabase (QA)</i>		OXCARBAZEPINE	
.Repatriation Schedule.....	1251	.NERVOUS SYSTEM.....	530
<i>Oratane (GN)</i>		<i>Oxis Turbuhaler (AP)</i>	
.DERMATOLOGICALS.....	197, 198	.RESPIRATORY SYSTEM.....	594
<i>Ordine 10 (MF)</i>		OXPRENOLOL	
.NERVOUS SYSTEM.....	513, 514	.CARDIOVASCULAR SYSTEM	128
<i>Ordine 2 (MF)</i>		OXYBUTYNIN	
.NERVOUS SYSTEM.....	513, 514	.GENITO URINARY SYSTEM AND SEX HORMONES .	212
<i>Ordine 5 (MF)</i>		<i>Oxybutynin Sandoz (SZ)</i>	
.NERVOUS SYSTEM.....	513, 514	.GENITO URINARY SYSTEM AND SEX HORMONES .	212
<i>Orencia (BQ)</i>		<i>Oxybutynin Winthrop (WA)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING		.GENITO URINARY SYSTEM AND SEX HORMONES .	212
AGENTS	311, 314	OXYCODONE	
.Section 100	791, 1049	.NERVOUS SYSTEM.....	514, 515
<i>Orgalutran (MK)</i>		OXYCODONE + NALOXONE	
.Section 100	1206	.NERVOUS SYSTEM.....	516
<i>Orion Temozolomide (ON)</i>		<i>Oxycodone Sandoz (SZ)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING		.NERVOUS SYSTEM.....	515, 516
AGENTS	256, 257	<i>OxyContin (MF)</i>	
<i>Oriprio (ON)</i>		.NERVOUS SYSTEM.....	516
.Section 100	1207	OXYMETAZOLINE	
ORLISTAT		.Repatriation Schedule.....	1267
.Repatriation Schedule.....	1245	<i>OxyNorm (MF)</i>	
<i>Oroxine (QA)</i>		.NERVOUS SYSTEM.....	515
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX		<i>OxyNorm Liquid 5mg/5mL (MF)</i>	
HORMONES AND INSULINS.....	219	.NERVOUS SYSTEM.....	515
<i>Orudis (SW)</i>		<i>Oxytocin Sandoz (SZ)</i>	
.MUSCULO-SKELETAL SYSTEM	493	.Prescriber Bag	57
<i>Orudis SR 200 (SW)</i>		<i>Oxytrol (GN)</i>	
.MUSCULO-SKELETAL SYSTEM	493	.GENITO URINARY SYSTEM AND SEX HORMONES .	212
<i>Oruvail SR (AV)</i>		<i>Ozapace (RA)</i>	
.MUSCULO-SKELETAL SYSTEM	493	.CARDIOVASCULAR SYSTEM	137
<i>OsmoLax (KY)</i>		<i>Ozcef (RA)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	74	.ANTIINFECTIVES FOR SYSTEMIC USE.....	234
.Palliative Care	664	<i>Oziclide MR (RA)</i>	
<i>Ospolot (PL)</i>		.ALIMENTARY TRACT AND METABOLISM.....	84
.NERVOUS SYSTEM.....	537	<i>Ozidal (RA)</i>	
<i>Ossmax 70mg (RA)</i>		.NERVOUS SYSTEM.....	556, 557, 558, 559
.MUSCULO-SKELETAL SYSTEM	498	<i>Ozin 10 (DO)</i>	
<i>Osteomol 665 Paracetamol (CR)</i>		.NERVOUS SYSTEM.....	547
.NERVOUS SYSTEM.....	524	<i>Ozin 2.5 (DO)</i>	
.Palliative Care	673, 674	.NERVOUS SYSTEM.....	549
<i>Otocomb Otic (FM)</i>		<i>Ozin 5 (DO)</i>	
.SENSORY ORGANS.....	624, 625	.NERVOUS SYSTEM.....	550

GENERIC/PROPRIETARY INDEX

<i>Ozin 7.5 (DO)</i>	
.NERVOUS SYSTEM.....	551
<i>Ozlodip (RA)</i>	
.CARDIOVASCULAR SYSTEM.....	132
<i>Ozmep (ZP)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	64
<i>Ozole (RA)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	246
<i>Ozpan (RA)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	65
<i>Ozvir (RA)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	250

P

<i>PAA (IQ)</i>		.ALIMENTARY TRACT AND METABOLISM.....	80, 81
.SENSORY ORGANS.....	619	PANCRELIPASE	
<i>Paediatric Seravit (SB)</i>		.ALIMENTARY TRACT AND METABOLISM.....	81
.VARIOUS.....	660	PANTHENOL	
<i>Palexia SR (CS)</i>		.Repatriation Schedule.....	1254
.NERVOUS SYSTEM.....	521	<i>Panthron (ER)</i>	
PALIPERIDONE		.ALIMENTARY TRACT AND METABOLISM.....	65
.NERVOUS SYSTEM.....	555	<i>Panto (TK)</i>	
PALONOSETRON		.ALIMENTARY TRACT AND METABOLISM.....	65
.ALIMENTARY TRACT AND METABOLISM.....	70	<i>Pantofast 20 (RZ)</i>	
<i>Pamacid 20 (AF)</i>		.ALIMENTARY TRACT AND METABOLISM.....	65
.ALIMENTARY TRACT AND METABOLISM.....	60	<i>Pantofast 40 (RZ)</i>	
<i>Pamacid 40 (AF)</i>		.ALIMENTARY TRACT AND METABOLISM.....	65
.ALIMENTARY TRACT AND METABOLISM.....	61	PANTOPRAZOLE	
PAMIDRONATE DISODIUM		.ALIMENTARY TRACT AND METABOLISM.....	64, 65
.MUSCULO-SKELETAL SYSTEM	499	<i>Pantoprazole Actavis (GN)</i>	
.Section 100	918, 1176, 1177	.ALIMENTARY TRACT AND METABOLISM.....	65
<i>Pamisol (HH)</i>		<i>Pantoprazole AN (EA)</i>	
.MUSCULO-SKELETAL SYSTEM	499	.ALIMENTARY TRACT AND METABOLISM.....	65
.Section 100	918, 919, 1176, 1177	<i>Pantoprazole generichealth (GQ)</i>	
<i>Panadeine Forte (SW)</i>		.ALIMENTARY TRACT AND METABOLISM.....	65, 66
.NERVOUS SYSTEM.....	516, 517	<i>Pantoprazole Sandoz (SZ)</i>	
<i>Panadol (GC)</i>		.ALIMENTARY TRACT AND METABOLISM.....	65, 66
.Palliative Care	673, 674	<i>Pantoprazole-GA (GN)</i>	
<i>Panadol Osteo (GC)</i>		.ALIMENTARY TRACT AND METABOLISM.....	65
.NERVOUS SYSTEM.....	524	<i>Pantoprazole-GA (UA)</i>	
.Palliative Care	673, 674	.ALIMENTARY TRACT AND METABOLISM.....	65, 66
<i>Panafcort (AS)</i>		<i>Panzytrat 25000 (TM)</i>	
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX		.ALIMENTARY TRACT AND METABOLISM.....	81
HORMONES AND INSULINS.....	218	PAPER WASP VENOM	
<i>Panafcortelone (AS)</i>		.VARIOUS.....	626
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX		PARACETAMOL	
HORMONES AND INSULINS.....	218	.NERVOUS SYSTEM.....	523, 524
<i>Panamax (SW)</i>		.Palliative Care.....	673
.NERVOUS SYSTEM.....	523, 524	<i>Paracetamol (Sandoz) (SZ)</i>	
<i>Panamax 240 Elixir (SW)</i>		.NERVOUS SYSTEM.....	523, 524
.NERVOUS SYSTEM.....	523	PARACETAMOL + CODEINE	
<i>Panamax Co. 40 (SW)</i>		.NERVOUS SYSTEM.....	516, 517
.Repatriation Schedule.....	1263	.Repatriation Schedule	1263
PANCREATIC EXTRACT		<i>Paracetamol/Codeine GH 500/30 (GQ)</i>	
		.NERVOUS SYSTEM.....	516, 517
		PARAFFIN	
		.SENSORY ORGANS.....	621, 622
		PARAFFIN LIGHT LIQUID + COCOAMPHODIACETATE	
		DISODIUM	
		.Repatriation Schedule	1254
		<i>Paralgin (FM)</i>	
		.NERVOUS SYSTEM.....	523, 524
		<i>Parapane (AF)</i>	
		.NERVOUS SYSTEM.....	523, 524
		<i>Pariet (JC)</i>	
		.ALIMENTARY TRACT AND METABOLISM.....	66
		<i>Parlodel (NV)</i>	
		.GENITO URINARY SYSTEM AND SEX HORMONES 200,	
		201	

GENERIC/PROPRIETARY INDEX

.NERVOUS SYSTEM.....	541	<i>Pemzo</i> (QA)	
<i>Parnate</i> (GH)		.ALIMENTARY TRACT AND METABOLISM.....	63, 64
.NERVOUS SYSTEM.....	569	PENICILLAMINE	
PAROXETINE		.MUSCULO-SKELETAL SYSTEM	496
.NERVOUS SYSTEM.....	568	<i>Pentasa</i> (FP)	
<i>Paroxetine Actavis</i> (UA)		.ALIMENTARY TRACT AND METABOLISM.....	78, 79
.NERVOUS SYSTEM.....	568	PENTASTARCH + SODIUM CHLORIDE	
<i>Paroxetine AN</i> (EA)		.BLOOD AND BLOOD FORMING ORGANS.....	119
.NERVOUS SYSTEM.....	568	<i>Penthrox</i> (DV)	
<i>Paroxetine generichealth</i> (GQ)		.Prescriber Bag	57
.NERVOUS SYSTEM.....	568	<i>Peptamen Junior</i> (NT)	
<i>Paroxetine Sandoz</i> (SZ)		.VARIOUS.....	648
.NERVOUS SYSTEM.....	568	<i>Pepzan</i> (GN)	
<i>Paroxetine-GA</i> (GN)		.ALIMENTARY TRACT AND METABOLISM.....	61
.NERVOUS SYSTEM.....	568	PERAMPANEL	
<i>Parzol 10</i> (ZP)		.NERVOUS SYSTEM.....	536
.ALIMENTARY TRACT AND METABOLISM.....	66	PERHEXILINE	
<i>Parzol 20</i> (ZP)		.CARDIOVASCULAR SYSTEM	124
.ALIMENTARY TRACT AND METABOLISM.....	66	<i>Periactin</i> (AS)	
<i>Paxam 0.5</i> (AF)		.NERVOUS SYSTEM.....	527
.NERVOUS SYSTEM.....	529	PERICYAZINE	
.Palliative Care	674	.NERVOUS SYSTEM.....	544
<i>Paxam 2</i> (AF)		<i>Perindo</i> (AF)	
.NERVOUS SYSTEM.....	528	.CARDIOVASCULAR SYSTEM	137
.Palliative Care	674	<i>Perindo Combi 4/1.25</i> (AF)	
<i>Paxtine</i> (AF)		.CARDIOVASCULAR SYSTEM	142
.NERVOUS SYSTEM.....	568	PERINDOPRIL	
PAZOPANIB		.CARDIOVASCULAR SYSTEM	136, 137
.ANTINEOPLASTIC AND IMMUNOMODULATING		PERINDOPRIL + AMLODIPINE	
AGENTS	283, 284, 285, 286	.CARDIOVASCULAR SYSTEM	142
<i>Peg 7420</i> (MM)		PERINDOPRIL + INDAPAMIDE	
.Repatriation Schedule	1274	.CARDIOVASCULAR SYSTEM	141
<i>Peg 7422</i> (MM)		<i>Perindopril Actavis 2</i> (UA)	
.Repatriation Schedule	1274	.CARDIOVASCULAR SYSTEM	137
<i>Peg 7423</i> (MM)		<i>Perindopril Actavis 4</i> (UA)	
.Repatriation Schedule	1274	.CARDIOVASCULAR SYSTEM	137
<i>Peg 7425</i> (MM)		<i>Perindopril Actavis 8</i> (UA)	
.Repatriation Schedule	1274	.CARDIOVASCULAR SYSTEM	137
<i>Pegasys</i> (RO)		<i>Perindopril and Indapamide CH 4/1.25</i> (EA)	
.Section 100	764, 1022	.CARDIOVASCULAR SYSTEM	142
<i>Pegasys RBV</i> (RO)		<i>Perindopril CH</i> (EA)	
.Section 100	768, 1026	.CARDIOVASCULAR SYSTEM	137
<i>Pegatron</i> (MK)		<i>Perindopril Combi Actavis 4/1.25</i> (GN)	
.Section 100	775, 780, 1033, 1038	.CARDIOVASCULAR SYSTEM	142
PEGFILGRASTIM		<i>Perindopril generichealth</i> (GQ)	
.Section 100	762, 1019	.CARDIOVASCULAR SYSTEM	137
PEGINTERFERON ALFA-2A		<i>Perindopril/ Indapamide GH 4/1.25</i> (GQ)	
.Section 100	764, 1021	.CARDIOVASCULAR SYSTEM	142
PEGINTERFERON ALFA-2A (&) RIBAVIRIN		PERMETHRIN	
.Section 100	764, 1022	.ANTIPARASITIC PRODUCTS, INSECTICIDES AND	
PEGINTERFERON ALFA-2B (&) RIBAVIRIN		REPELLENTS.....	593
.Section 100	769, 776, 1026, 1034	<i>Persantin SR</i> (BY)	
PEGINTERFERON BETA-1A		.BLOOD AND BLOOD FORMING ORGANS.....	108
.ANTINEOPLASTIC AND IMMUNOMODULATING		<i>Petrus Bisacodyl Suppositories</i> (PP)	
AGENTS	302, 303	.ALIMENTARY TRACT AND METABOLISM.....	73

GENERIC/PROPRIETARY INDEX

.Palliative Care	662, 663	<i>Pharmacor Gabapentin 800 (CR)</i>	
<i>Petrus Pharmaceuticals Pty Ltd (PP)</i>		.NERVOUS SYSTEM.....	532
.ALIMENTARY TRACT AND METABOLISM.....	76	<i>Pharmacor Letrozole 2.5 (CR)</i>	
.Palliative Care	666	.ANTINEOPLASTIC AND IMMUNOMODULATING	
.Repatriation Schedule.....	1245	AGENTS	299
<i>Pexsig (QA)</i>		<i>Pharmacor Meloxicam 15 (CR)</i>	
.CARDIOVASCULAR SYSTEM	124	.MUSCULO-SKELETAL SYSTEM	491
<i>Pfizer Australia Pty Ltd (PF)</i>		<i>Pharmacor Meloxicam 7.5 (CR)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	67	.MUSCULO-SKELETAL SYSTEM	492
.ANTIINFECTIVES FOR SYSTEMIC USE.....	240, 242	<i>Pharmacor Metformin 1000 (CR)</i>	
.BLOOD AND BLOOD FORMING ORGANS	105	.ALIMENTARY TRACT AND METABOLISM.....	83
.Prescriber Bag	56, 57	<i>Pharmacor Montelukast 4 (CR)</i>	
<i>Pharmacor Amlodipine (CR)</i>		.RESPIRATORY SYSTEM.....	603
.CARDIOVASCULAR SYSTEM	132	<i>Pharmacor Montelukast 5 (CR)</i>	
<i>Pharmacor AmoxyClav 500/125 (CR)</i>		.RESPIRATORY SYSTEM.....	604
.ANTIINFECTIVES FOR SYSTEMIC USE.....	229, 230	<i>Pharmacor Mycophenolate 250 (CR)</i>	
<i>Pharmacor AmoxyClav 875/125 (CR)</i>		.ANTINEOPLASTIC AND IMMUNOMODULATING	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	230	AGENTS	316
<i>Pharmacor Anastrozole 1 (CR)</i>		.Section 100.....	802, 1061
.ANTINEOPLASTIC AND IMMUNOMODULATING		<i>Pharmacor Mycophenolate 500 (CR)</i>	
AGENTS	297	.ANTINEOPLASTIC AND IMMUNOMODULATING	
<i>Pharmacor Candesartan 16 (CR)</i>		AGENTS	316
.CARDIOVASCULAR SYSTEM	144	.Section 100.....	803, 1061
<i>Pharmacor Candesartan 32 (CR)</i>		<i>Pharmacor Olanzapine 10 (CR)</i>	
.CARDIOVASCULAR SYSTEM	144	.NERVOUS SYSTEM.....	547
<i>Pharmacor Candesartan 4 (CR)</i>		<i>Pharmacor Olanzapine 2.5 (CR)</i>	
.CARDIOVASCULAR SYSTEM	144	.NERVOUS SYSTEM.....	549
<i>Pharmacor Candesartan 8 (CR)</i>		<i>Pharmacor Olanzapine 5 (CR)</i>	
.CARDIOVASCULAR SYSTEM	144	.NERVOUS SYSTEM.....	550
<i>Pharmacor Candesartan HCT 16/12.5 (CR)</i>		<i>Pharmacor Olanzapine 7.5 (CR)</i>	
.CARDIOVASCULAR SYSTEM	147	.NERVOUS SYSTEM.....	551
<i>Pharmacor Candesartan HCT 32/12.5 (CR)</i>		<i>Pharmacor Omeprazole 20 (CR)</i>	
.CARDIOVASCULAR SYSTEM	148	.ALIMENTARY TRACT AND METABOLISM.....	63, 64
<i>Pharmacor Candesartan HCT 32/25 (CR)</i>		<i>Pharmacor Pioglitazone 15 (CR)</i>	
.CARDIOVASCULAR SYSTEM	148	.ALIMENTARY TRACT AND METABOLISM.....	92
<i>Pharmacor Cephalexin 500 (CR)</i>		<i>Pharmacor Pioglitazone 30 (CR)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	232	.ALIMENTARY TRACT AND METABOLISM.....	92
<i>Pharmacor Citalo 20 (CR)</i>		<i>Pharmacor Pioglitazone 45 (CR)</i>	
.NERVOUS SYSTEM.....	564	.ALIMENTARY TRACT AND METABOLISM.....	92
<i>Pharmacor Donepezil 10 (CR)</i>		<i>Pharmacor Pravastat 10 (CR)</i>	
.NERVOUS SYSTEM.....	576, 578	.CARDIOVASCULAR SYSTEM	159, 160
<i>Pharmacor Donepezil 5 (CR)</i>		<i>Pharmacor Pravastat 20 (CR)</i>	
.NERVOUS SYSTEM.....	577, 578	.CARDIOVASCULAR SYSTEM	159, 161
<i>Pharmacor Duloxetine 30 (CR)</i>		<i>Pharmacor Pravastat 40 (CR)</i>	
.NERVOUS SYSTEM.....	570	.CARDIOVASCULAR SYSTEM	160, 161
<i>Pharmacor Duloxetine 60 (CR)</i>		<i>Pharmacor Prozone 5 (CR)</i>	
.NERVOUS SYSTEM.....	571	.ALIMENTARY TRACT AND METABOLISM.....	72
<i>Pharmacor Escitalopram 10 (CR)</i>		<i>Pharmacor Quetiapine 100 (CR)</i>	
.NERVOUS SYSTEM.....	565	.NERVOUS SYSTEM.....	552
<i>Pharmacor Escitalopram 20 (CR)</i>		<i>Pharmacor Quetiapine 200 (CR)</i>	
.NERVOUS SYSTEM.....	565	.NERVOUS SYSTEM.....	552
<i>Pharmacor Finasteride 5 (CR)</i>		<i>Pharmacor Quetiapine 25 (CR)</i>	
.Repatriation Schedule.....	1258	.NERVOUS SYSTEM.....	554
<i>Pharmacor Gabapentin 600 (CR)</i>		<i>Pharmacor Quetiapine 300 (CR)</i>	
.NERVOUS SYSTEM.....	532	.NERVOUS SYSTEM.....	553

GENERIC/PROPRIETARY INDEX

<i>Pharmacor Ramipril 10 (CR)</i>	
.CARDIOVASCULAR SYSTEM	139
<i>Pharmacor Ramipril 5 (CR)</i>	
.CARDIOVASCULAR SYSTEM	140
<i>Pharmacor Riluzole (CR)</i>	
.NERVOUS SYSTEM	590
<i>Pharmacor Salbutamol 2.5 (CR)</i>	
.Prescriber Bag	57
.RESPIRATORY SYSTEM	595
<i>Pharmacor Salbutamol 5 (CR)</i>	
.Prescriber Bag	58
.RESPIRATORY SYSTEM	595
<i>Pharmacor Sumatriptan 50 (CR)</i>	
.NERVOUS SYSTEM	526
<i>Pharmacor Tacrolimus 0.5 (CR)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	488
.Section 100	904, 1162
<i>Pharmacor Tacrolimus 1 (CR)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	488
.Section 100	903, 1162
<i>Pharmacor Tacrolimus 5 (CR)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	488
.Section 100	904, 1162
<i>Pharmacor Telmisartan 40 (CR)</i>	
.CARDIOVASCULAR SYSTEM	146
<i>Pharmacor Telmisartan 80 (CR)</i>	
.CARDIOVASCULAR SYSTEM	146
<i>Pharmacy Action Anti-Fungal Cream (GQ)</i>	
.Repatriation Schedule	1250
<i>Pharmacy Action Cetrelief (GQ)</i>	
.Repatriation Schedule	1268
<i>Pharmacy Action FemCream (GQ)</i>	
.Repatriation Schedule	1256
<i>Pharmacy Action Laxative with Senna (GQ)</i>	
.Repatriation Schedule	1245
<i>Pharmacy Action Lorastyne (GQ)</i>	
.Repatriation Schedule	1268
<i>Pharmacy Action Low Dose Aspirin (GQ)</i>	
.Repatriation Schedule	1248
<i>Pharmacy Action Paracetamol Plus Codeine (GQ)</i>	
.Repatriation Schedule	1263
<i>Pharmacy Action Sinus & Nasal Decongestant Relief (GQ)</i>	
.Repatriation Schedule	1267
<i>Pharmacy Choice Anastrozole (RI)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	297
<i>Pharmacy Choice Finasteride (RI)</i>	
.Repatriation Schedule	1258
<i>Pharmacy Choice Letrozole (RI)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	299
<i>Pharmacy Choice Olanzapine (RI)</i>	
.NERVOUS SYSTEM	547, 549, 550, 552
<i>Pharmacy Choice Olanzapine ODT (RI)</i>	
.NERVOUS SYSTEM	546
<i>Pharmacy Choice Quetiapine (RI)</i>	
.NERVOUS SYSTEM	552, 553, 554
<i>Pharmacy Choice Terbinafine (RI)</i>	
.DERMATOLOGICALS	193
<i>Phebra Naproxen Suspension (PL)</i>	
.MUSCULO-SKELETAL SYSTEM	494
.Palliative Care	669, 670
PHENELZINE	
.NERVOUS SYSTEM	569
PHENOBARBITONE	
.NERVOUS SYSTEM	527
PHENOXYBENZAMINE	
.CARDIOVASCULAR SYSTEM	128
.GENITO URINARY SYSTEM AND SEX HORMONES	212
PHENOXYMETHYLPENICILLIN	
.ANTIINFECTIVES FOR SYSTEMIC USE	227, 228
<i>Phenoxymethylpenicillin-AFT (AE)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE	227
<i>Phenylalanine 50 (VF)</i>	
.VARIOUS	658
PHENYLALANINE WITH CARBOHYDRATE	
.VARIOUS	658
PHENYLEPHRINE + PREDNISOLONE ACETATE	
.SENSORY ORGANS	607
PHENYTOIN	
.NERVOUS SYSTEM	528
<i>Phlexy-10 (SB)</i>	
.VARIOUS	651
<i>Phlexy-10 Drink Mix (SB)</i>	
.VARIOUS	651
PHOLCODINE	
.Repatriation Schedule	1267
<i>Phosphate Sandoz (NV)</i>	
.VARIOUS	628
PHOSPHORUS	
.VARIOUS	628
<i>Physeptone (QA)</i>	
.NERVOUS SYSTEM	520
<i>Physiotens (GO)</i>	
.CARDIOVASCULAR SYSTEM	125
<i>Piax (AF)</i>	
.BLOOD AND BLOOD FORMING ORGANS	106, 107
.Repatriation Schedule	1248
<i>Piax Plus Aspirin (AF)</i>	
.BLOOD AND BLOOD FORMING ORGANS	108
<i>Picato (LO)</i>	
.Repatriation Schedule	1252, 1253
PILOCARPINE	
.SENSORY ORGANS	609
PIMECROLIMUS	
.DERMATOLOGICALS	198
PINDOLOL	

GENERIC/PROPRIETARY INDEX

.CARDIOVASCULAR SYSTEM	128	<i>Plaquenil (SW)</i>	
PINE TAR WITH TRIETHANOLAMINE LAURYL SULFATE		.MUSCULO-SKELETAL SYSTEM	495
.Repatriation Schedule	1252	<i>Plasma-Lyte 148 (BX)</i>	
<i>Pinetarsol (EO)</i>		.BLOOD AND BLOOD FORMING ORGANS.....	120
.Repatriation Schedule	1252	<i>Plavitor 75 (CR)</i>	
PIOGLITAZONE		.BLOOD AND BLOOD FORMING ORGANS.....	107
.ALIMENTARY TRACT AND METABOLISM.....	90	<i>Plavix (SW)</i>	
<i>Pioglitazone AN (EA)</i>		.BLOOD AND BLOOD FORMING ORGANS.....	106, 107
.ALIMENTARY TRACT AND METABOLISM.....	92	.Repatriation Schedule	1248
<i>Pioglitazone generichealth 15 (GQ)</i>		<i>Plegridy (BD)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	92	.ANTINEOPLASTIC AND IMMUNOMODULATING	
<i>Pioglitazone generichealth 30 (GQ)</i>		AGENTS	302, 303
.ALIMENTARY TRACT AND METABOLISM.....	92	<i>Plendil ER (GX)</i>	
<i>Pioglitazone generichealth 45 (GQ)</i>		.CARDIOVASCULAR SYSTEM	132, 133
.ALIMENTARY TRACT AND METABOLISM.....	92	PLERIXAFOR	
<i>Pioglitazone Sandoz (SZ)</i>		.Section 100.....	780, 1038
.ALIMENTARY TRACT AND METABOLISM.....	92	<i>Plidogrel (FM)</i>	
<i>Pioglitazone-GA (GN)</i>		.BLOOD AND BLOOD FORMING ORGANS.....	106, 108
.ALIMENTARY TRACT AND METABOLISM.....	92	PNEUMOCOCCAL PURIFIED CAPSULAR	
PIROXICAM		POLYSACCHARIDES	
.MUSCULO-SKELETAL SYSTEM	492	.ANTIINFECTIVES FOR SYSTEMIC USE	255
<i>Pizaccord (RA)</i>		<i>Pneumovax 23 (CS)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	92	.ANTIINFECTIVES FOR SYSTEMIC USE	255
PIZOTIFEN		PODOPHYLLOTOXIN	
.NERVOUS SYSTEM.....	527	.Repatriation Schedule	1252
<i>PKU Anamix infant (SB)</i>		<i>Poly Gel (AQ)</i>	
.VARIOUS.....	651	.SENSORY ORGANS.....	618
<i>PKU Anamix Junior (SB)</i>		<i>Poly Visc (IQ)</i>	
.VARIOUS.....	653	.SENSORY ORGANS.....	621, 622
<i>PKU Anamix Junior LQ (SB)</i>		POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL	
.VARIOUS.....	653	.SENSORY ORGANS.....	622, 623
<i>PKU Cooler 10 (VF)</i>		POLYLACTIC ACID	
.VARIOUS.....	653	.VARIOUS.....	628
<i>PKU Cooler 15 (VF)</i>		POLYSTYRENE SULFONATE SODIUM	
.VARIOUS.....	653	.Repatriation Schedule	1270
<i>PKU Cooler 20 (VF)</i>		<i>Polytar (GK)</i>	
.VARIOUS.....	653	.Repatriation Schedule	1253
<i>PKU express 15 (VF)</i>		<i>Poly-Tears (IQ)</i>	
.VARIOUS.....	653	.SENSORY ORGANS.....	620
<i>PKU express 20 (VF)</i>		POLYVINYL ALCOHOL	
.VARIOUS.....	653	.SENSORY ORGANS.....	623
<i>PKU gel (VF)</i>		<i>Ponstan (PF)</i>	
.VARIOUS.....	653	.MUSCULO-SKELETAL SYSTEM	494
<i>PKU Lophlex LQ 10 (SB)</i>		POSACONAZOLE	
.VARIOUS.....	653	.ANTIINFECTIVES FOR SYSTEMIC USE	247
<i>PKU Lophlex LQ 20 (SB)</i>		POTASSIUM CHLORIDE	
.VARIOUS.....	653	.ALIMENTARY TRACT AND METABOLISM.....	101
<i>PKU Lophlex Sensation 20 (SB)</i>		POTASSIUM CHLORIDE + POTASSIUM BICARBONATE +	
.VARIOUS.....	653	POTASSIUM CARBONATE	
<i>PKU squeezie (VF)</i>		.ALIMENTARY TRACT AND METABOLISM.....	101
.VARIOUS.....	653	POVIDONE-IODINE	
<i>Placil (AF)</i>		.Repatriation Schedule	1253
.NERVOUS SYSTEM.....	563	<i>Prabez (AF)</i>	
<i>Plaqacide (OB)</i>		.ALIMENTARY TRACT AND METABOLISM.....	66
.Repatriation Schedule	1244	<i>Pradaxa (BY)</i>	

GENERIC/PROPRIETARY INDEX

.BLOOD AND BLOOD FORMING ORGANS	111, 112
<i>Pramin (AF)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	67
PRAMIPEXOLE	
.NERVOUS SYSTEM.....	541, 542
<i>Pramipexole AN (EA)</i>	
.NERVOUS SYSTEM.....	541
<i>Pramipexole GH (GQ)</i>	
.NERVOUS SYSTEM.....	541
PRASUGREL	
.BLOOD AND BLOOD FORMING ORGANS	109
<i>Pravachol (FM)</i>	
.CARDIOVASCULAR SYSTEM.....	159, 160, 161
PRAVASTATIN	
.CARDIOVASCULAR SYSTEM.....	159, 160
<i>Pravastatin Actavis 10 (UA)</i>	
.CARDIOVASCULAR SYSTEM.....	159, 160
<i>Pravastatin Actavis 20 (UA)</i>	
.CARDIOVASCULAR SYSTEM.....	159, 161
<i>Pravastatin Actavis 40 (UA)</i>	
.CARDIOVASCULAR SYSTEM.....	160, 161
<i>Pravastatin AN (EA)</i>	
.CARDIOVASCULAR SYSTEM.....	159, 160, 161
<i>Pravastatin generichealth (GQ)</i>	
.CARDIOVASCULAR SYSTEM.....	159, 160, 161
<i>Pravastatin Sandoz (SZ)</i>	
.CARDIOVASCULAR SYSTEM.....	159, 160, 161
<i>Pravastatin-GA 10 (GN)</i>	
.CARDIOVASCULAR SYSTEM.....	159, 160
<i>Pravastatin-GA 20 (GN)</i>	
.CARDIOVASCULAR SYSTEM.....	160, 161
<i>Pravastatin-GA 40 (GN)</i>	
.CARDIOVASCULAR SYSTEM.....	160, 161
<i>Pravastatin-GA 80 (GN)</i>	
.CARDIOVASCULAR SYSTEM.....	160, 161
PRAZIQUANTEL	
.ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS.....	592
PRAZOSIN	
.CARDIOVASCULAR SYSTEM.....	125
<i>PredMix (LN)</i>	
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS.....	218
<i>Prednefrin Forte (AG)</i>	
.SENSORY ORGANS.....	607, 608
PREDNISOLONE	
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS.....	218
PREDNISOLONE SODIUM PHOSPHATE	
.ALIMENTARY TRACT AND METABOLISM.....	77
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS.....	218
PREDNISON	
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS.....	218
<i>Predsol (QA)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	77, 78
<i>Predsolone (LN)</i>	
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS.....	218
<i>Predsone (LN)</i>	
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS.....	218
PREGABALIN	
.NERVOUS SYSTEM.....	524
<i>Pregnyl (MK)</i>	
.GENITO URINARY SYSTEM AND SEX HORMONES .	210
.Section 100.....	1206
<i>Presolol 100 (AF)</i>	
.CARDIOVASCULAR SYSTEM	132
<i>Presolol 200 (AF)</i>	
.CARDIOVASCULAR SYSTEM	132
<i>Prexaton (GN)</i>	
.NERVOUS SYSTEM.....	584
<i>PREXUM 10 (RX)</i>	
.CARDIOVASCULAR SYSTEM	137
<i>PREXUM 2.5 (RX)</i>	
.CARDIOVASCULAR SYSTEM	137
<i>PREXUM 5 (RX)</i>	
.CARDIOVASCULAR SYSTEM	137
<i>Prexum Combi 5/1.25 (RX)</i>	
.CARDIOVASCULAR SYSTEM	141
<i>Prezista (JC)</i>	
.Section 100.....	740, 996
<i>Prilace 10 (QA)</i>	
.CARDIOVASCULAR SYSTEM	139
<i>Prilace 2.5 (QA)</i>	
.CARDIOVASCULAR SYSTEM	139
<i>Prilace 5 (QA)</i>	
.CARDIOVASCULAR SYSTEM	140
PRIMIDONE	
.NERVOUS SYSTEM.....	528
<i>Primolut N (BN)</i>	
.GENITO URINARY SYSTEM AND SEX HORMONES .	208
<i>Primoteston Depot (BN)</i>	
.GENITO URINARY SYSTEM AND SEX HORMONES .	205
<i>Prinivil 10 (MK)</i>	
.CARDIOVASCULAR SYSTEM	136
<i>Prinivil 20 (MK)</i>	
.CARDIOVASCULAR SYSTEM	136
<i>Prioten 15 (DO)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	92
<i>Prioten 30 (DO)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	92
<i>Prioten 45 (DO)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	92
<i>Pristiq (PF)</i>	
.NERVOUS SYSTEM.....	570
<i>Pritor Plus 40/12.5 mg (FI)</i>	
.CARDIOVASCULAR SYSTEM	150

GENERIC/PROPRIETARY INDEX

<i>Pritor Plus 80/12.5 mg (FI)</i>		
.CARDIOVASCULAR SYSTEM	150	
<i>Pritor Plus 80/25 mg (FI)</i>		
.CARDIOVASCULAR SYSTEM	151	
<i>Pritor/Amlodipine (FI)</i>		
.CARDIOVASCULAR SYSTEM	152	
<i>Pro-Banthine (QA)</i>		
.GENITO URINARY SYSTEM AND SEX HORMONES .	212	
PROBENECID		
.MUSCULO-SKELETAL SYSTEM	497	
<i>Probitor (SZ)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	64	
PROCAINE PENICILLIN		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	228	
<i>ProCalm (QA)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	72	
PROCHLORPERAZINE		
.ALIMENTARY TRACT AND METABOLISM.....	72	
<i>Prochlorperazine AN (EA)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	72	
<i>Prochlorperazine GH (GQ)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	72	
<i>Prochlorperazine-GA (GN)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	72	
<i>Pro-Cid (PL)</i>		
.MUSCULO-SKELETAL SYSTEM	497	
<i>Procur (GN)</i>		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	295	
.GENITO URINARY SYSTEM AND SEX HORMONES .	211	
<i>Procur 100 (GN)</i>		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	295	
.GENITO URINARY SYSTEM AND SEX HORMONES .	211	
<i>Prodeine 15 (SW)</i>		
.Repatriation Schedule	1263	
<i>Prodeine Forte (AV)</i>		
.NERVOUS SYSTEM.....	516, 517	
<i>Profore 66050016 (SN)</i>		
.Repatriation Schedule	1274	
<i>Profore Lite 66050415 (SN)</i>		
.Repatriation Schedule	1274	
PROGESTERONE		
.Section 100	1206, 1207	
<i>Progout 100 (AF)</i>		
.MUSCULO-SKELETAL SYSTEM	497	
<i>Progout 300 (AF)</i>		
.MUSCULO-SKELETAL SYSTEM	497	
<i>Prograf (LL)</i>		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	488	
.Section 100	904, 1162	
<i>Prograf XL (LL)</i>		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	488	
.Section 100.....	904, 1162	
<i>Progynova (BN)</i>		
.GENITO URINARY SYSTEM AND SEX HORMONES .	207	
<i>Proladone (PL)</i>		
.NERVOUS SYSTEM.....	515	
<i>Prolia (AN)</i>		
.MUSCULO-SKELETAL SYSTEM	508	
PROMETHAZINE		
.ALIMENTARY TRACT AND METABOLISM.....	72	
.RESPIRATORY SYSTEM.....	604	
<i>Prontosan Wound Irrigation Solution (BR)</i>		
.Repatriation Schedule	1276	
PROPANTHELINE		
.GENITO URINARY SYSTEM AND SEX HORMONES .	212	
PROPRANOLOL		
.CARDIOVASCULAR SYSTEM	128	
PROPYLTHIOURACIL		
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX		
HORMONES AND INSULINS.....	219	
<i>Proscar (MK)</i>		
.Repatriation Schedule	1258	
<i>Protaphane (NO)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	82	
<i>Protaphane InnoLet (NI)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	82	
<i>Protaphane Penfill 3 mL (NO)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	82	
PROTEIN HYDROLYSATE FORMULA WITH MEDIUM		
CHAIN TRIGLYCERIDES		
.VARIOUS.....	644, 646	
<i>Protos 2 g (SE)</i>		
.MUSCULO-SKELETAL SYSTEM	509	
<i>Provera (PF)</i>		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	291, 292	
.GENITO URINARY SYSTEM AND SEX HORMONES .	208	
<i>Proxen SR 1000 (MD)</i>		
.MUSCULO-SKELETAL SYSTEM	493	
.Palliative Care.....	669	
<i>Proxen SR 750 (MD)</i>		
.MUSCULO-SKELETAL SYSTEM	494	
.Palliative Care.....	669	
<i>Prozac 20 (LY)</i>		
.NERVOUS SYSTEM.....	567	
<i>Prozac Tab (LY)</i>		
.NERVOUS SYSTEM.....	567	
<i>ProZero (VF)</i>		
.VARIOUS.....	659	
PSEUDOEPHEDRINE		
.Repatriation Schedule	1267	
PSYLLIUM HUSK POWDER		
.Repatriation Schedule	1245	
PTU (PL)		
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX		
HORMONES AND INSULINS.....	219	

GENERIC/PROPRIETARY INDEX

<i>Pulmicort Respules (AP)</i>	
.RESPIRATORY SYSTEM	600
<i>Pulmicort Turbuhaler (AP)</i>	
.RESPIRATORY SYSTEM	600, 601
<i>Pulmozyme (RO)</i>	
.Section 100	928, 1191
<i>Puregon 300 IU/0.36 mL (MK)</i>	
.GENITO URINARY SYSTEM AND SEX HORMONES .	209
.Section 100	1205
<i>Puregon 600 IU/0.72 mL (MK)</i>	
.GENITO URINARY SYSTEM AND SEX HORMONES .	210
.Section 100	1206
<i>Puregon 900 IU/1.08 mL (MK)</i>	
.GENITO URINARY SYSTEM AND SEX HORMONES .	210
.Section 100	1206
<i>Purinethol (AS)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	258
<i>PVA Tears (PE)</i>	
.SENSORY ORGANS.....	623
<i>Pyralin EN (FZ)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	80
PYRANTEL	
.ANTIPARASITIC PRODUCTS, INSECTICIDES AND	
REPELLENTS.....	592
PYRIDOSTIGMINE	
.NERVOUS SYSTEM.....	584
PYRIMETHAMINE	
.ANTIPARASITIC PRODUCTS, INSECTICIDES AND	
REPELLENTS.....	591

Q

<i>Qpril 10 (AF)</i>	
.CARDIOVASCULAR SYSTEM	138
<i>Qpril 20 (AF)</i>	
.CARDIOVASCULAR SYSTEM	138
<i>Qpril 5 (AF)</i>	
.CARDIOVASCULAR SYSTEM	138
<i>Questran Lite (QA)</i>	
.CARDIOVASCULAR SYSTEM	169, 170
<i>Quetia 100 (FM)</i>	
.NERVOUS SYSTEM.....	552
<i>Quetia 200 (FM)</i>	
.NERVOUS SYSTEM.....	552
<i>Quetia 25 (FM)</i>	
.NERVOUS SYSTEM.....	554
<i>Quetia 300 (FM)</i>	
.NERVOUS SYSTEM.....	553
<i>Quetiaccord (UA)</i>	
.NERVOUS SYSTEM.....	552, 553, 554
QUETIAPINE	
.NERVOUS SYSTEM.....	552, 553
<i>Quetiapine Actavis 100 (VN)</i>	
.NERVOUS SYSTEM.....	552
<i>Quetiapine Actavis 200 (VN)</i>	
.NERVOUS SYSTEM.....	552
<i>Quetiapine Actavis 25 (VN)</i>	
.NERVOUS SYSTEM.....	554
<i>Quetiapine Actavis 300 (VN)</i>	
.NERVOUS SYSTEM.....	553
<i>Quetiapine AN (EA)</i>	
.NERVOUS SYSTEM.....	552, 553, 554
<i>Quetiapine GH 100 (GQ)</i>	
.NERVOUS SYSTEM.....	552
<i>Quetiapine GH 200 (GQ)</i>	
.NERVOUS SYSTEM.....	552
<i>Quetiapine GH 25 (GQ)</i>	
.NERVOUS SYSTEM.....	554
<i>Quetiapine GH 300 (GQ)</i>	
.NERVOUS SYSTEM.....	553
<i>Quetiapine RBX (RA)</i>	
.NERVOUS SYSTEM.....	552, 553, 554
<i>Quetiapine Sandoz (SZ)</i>	
.NERVOUS SYSTEM.....	552, 553, 554
<i>Quetiapine-DRLA (RZ)</i>	
.NERVOUS SYSTEM.....	552, 553, 554
<i>Quetiapine-GA (GN)</i>	
.NERVOUS SYSTEM.....	552, 553, 554
<i>Quilonum SR (AS)</i>	
.NERVOUS SYSTEM.....	571
QUINAGOLIDE	
.GENITO URINARY SYSTEM AND SEX HORMONES .	201
QUINAPRIL	
.CARDIOVASCULAR SYSTEM	138
QUINAPRIL + HYDROCHLOROTHIAZIDE	
.CARDIOVASCULAR SYSTEM	142
<i>Quinapril generichealth (GQ)</i>	
.CARDIOVASCULAR SYSTEM	138
<i>Quinapril-GA (UA)</i>	
.CARDIOVASCULAR SYSTEM	138
<i>Quinate (AS)</i>	
.ANTIPARASITIC PRODUCTS, INSECTICIDES AND	
REPELLENTS.....	591
QUININE	
.ANTIPARASITIC PRODUCTS, INSECTICIDES AND	
REPELLENTS.....	591
<i>QuitX (AF)</i>	
.Repatriation Schedule	1265
<i>QV Bath Oil (EO)</i>	
.Repatriation Schedule	1251
<i>Qvar 100 (IA)</i>	
.RESPIRATORY SYSTEM.....	600
<i>Qvar 100 Autohaler (IA)</i>	
.RESPIRATORY SYSTEM.....	600
<i>Qvar 50 (IA)</i>	
.RESPIRATORY SYSTEM.....	600
<i>Qvar 50 Autohaler (IA)</i>	
.RESPIRATORY SYSTEM.....	600

GENERIC/PROPRIETARY INDEX

R

RABEPRAZOLE	
.ALIMENTARY TRACT AND METABOLISM.....	66
<i>Rabeprazole Actavis 20 (UA)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	66
<i>Rabeprazole AN (EA)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	66
<i>Rabeprazole generichealth (GQ)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	66, 67
<i>Rabeprazole RBX (RA)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	66, 67
<i>Rabeprazole Sandoz (SZ)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	66, 67
<i>Rabeprazole-DRLA (RZ)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	66, 67
<i>Rabeprazole-GA (GN)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	66
<i>Ralovera (FZ)</i>	
.GENITO URINARY SYSTEM AND SEX HORMONES .	208
RALOXIFENE	
.MUSCULO-SKELETAL SYSTEM	508
<i>Raloxifene AN (EA)</i>	
.MUSCULO-SKELETAL SYSTEM	508
RALTEGRAVIR	
.Section 100	755, 1012, 1013
<i>Ramace 1.25 mg (AV)</i>	
.CARDIOVASCULAR SYSTEM	138
<i>Ramace 10 mg (AV)</i>	
.CARDIOVASCULAR SYSTEM	139
<i>Ramace 2.5 mg (AV)</i>	
.CARDIOVASCULAR SYSTEM	139
<i>Ramace 5 mg (AV)</i>	
.CARDIOVASCULAR SYSTEM	140
RAMIPRIL	
.CARDIOVASCULAR SYSTEM	138, 139, 140
RAMIPRIL + FELODIPINE	
.CARDIOVASCULAR SYSTEM	143
<i>Ramipril AN (EA)</i>	
.CARDIOVASCULAR SYSTEM	138, 139, 140
<i>Ramipril CH (EA)</i>	
.CARDIOVASCULAR SYSTEM	139
<i>Ramipril generichealth (GQ)</i>	
.CARDIOVASCULAR SYSTEM	139, 140
<i>Ramipril RBX Tabs (RA)</i>	
.CARDIOVASCULAR SYSTEM	139, 140
<i>Ramipril Sandoz (SZ)</i>	
.CARDIOVASCULAR SYSTEM	138, 139, 140
<i>Ramipril Winthrop (WA)</i>	
.CARDIOVASCULAR SYSTEM	138, 139, 140
<i>Ramipril-GA (GN)</i>	
.CARDIOVASCULAR SYSTEM	138, 139, 140
<i>Rancef (RA)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	231, 232, 233
<i>Rani 2 (AF)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	61
RANIBIZUMAB	
.SENSORY ORGANS.....	616
RANITIDINE	
.ALIMENTARY TRACT AND METABOLISM.....	61
<i>Ranitidine AN (EA)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	61
<i>Ranitidine GH (GQ)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	61
<i>Ranitidine Sandoz (SZ)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	61
<i>Ranmoxy (RA)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE	225, 226
<i>Ranoxyl (GN)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	61
<i>Ransim (RA)</i>	
.CARDIOVASCULAR SYSTEM	166, 167, 168
<i>Ranzepam (RA)</i>	
.NERVOUS SYSTEM	560, 561
.Palliative Care.....	674, 675
<i>Rapamune (PF)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	316
.Section 100.....	803, 1061
<i>Rapilysin 10 U (GN)</i>	
.BLOOD AND BLOOD FORMING ORGANS.....	110
RASAGILINE	
.NERVOUS SYSTEM	543
<i>Razit 10 (DO)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	66
<i>Razit 20 (DO)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	66, 67
<i>RBX Topiramate (RA)</i>	
.NERVOUS SYSTEM	537, 538
RCF (AB)	
.VARIOUS.....	658
<i>Reandron 1000 (BN)</i>	
.GENITO URINARY SYSTEM AND SEX HORMONES .	206
<i>Reaptan 10/10 (RX)</i>	
.CARDIOVASCULAR SYSTEM	143
<i>Reaptan 10/5 (RX)</i>	
.CARDIOVASCULAR SYSTEM	143
<i>Reaptan 5/10 (RX)</i>	
.CARDIOVASCULAR SYSTEM	143
<i>Reaptan 5/5 (RX)</i>	
.CARDIOVASCULAR SYSTEM	143
<i>Rebif 44 (SG)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	301
REBOXETINE	
.NERVOUS SYSTEM	572
<i>ReddyMax Plus D-Cal (RZ)</i>	
.MUSCULO-SKELETAL SYSTEM	504
<i>Redipred (AS)</i>	

GENERIC/PROPRIETARY INDEX

.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS.....	218
<i>Reedos 100 (DO)</i>	
.NERVOUS SYSTEM.....	534
<i>Reedos 200 (DO)</i>	
.NERVOUS SYSTEM.....	534
<i>Reedos 25 (DO)</i>	
.NERVOUS SYSTEM.....	534
<i>Reedos 50 (DO)</i>	
.NERVOUS SYSTEM.....	535
<i>Refresh Liquigel (AG)</i>	
.SENSORY ORGANS.....	619
<i>Refresh Night Time (AG)</i>	
.SENSORY ORGANS.....	621, 622
<i>Refresh Tears Plus (AG)</i>	
.SENSORY ORGANS.....	619
<i>Relistor (LM)</i>	
.Palliative Care	666
<i>Relpax (PF)</i>	
.NERVOUS SYSTEM.....	525
<i>Remeron SolTab (FR)</i>	
.NERVOUS SYSTEM.....	571, 572
<i>Remicade (JC)</i>	
.Repatriation Schedule.....	1260
.Section 100 ...	820, 824, 834, 840, 847, 849, 859, 865, 869, 1079, 1082, 1088, 1098, 1100, 1107, 1117, 1123, 1127
<i>Reminyl (JC)</i>	
.NERVOUS SYSTEM.....	579, 580
<i>Renagel (GZ)</i>	
.Section 100	934, 1197
.VARIOUS.....	627
<i>Renastart (VF)</i>	
.VARIOUS.....	660
<i>RenaStart (VF)</i>	
.VARIOUS.....	660
<i>Renitec (MK)</i>	
.CARDIOVASCULAR SYSTEM	135
<i>Renitec 20 (MK)</i>	
.CARDIOVASCULAR SYSTEM	135
<i>Renitec Plus 20/6 (MK)</i>	
.CARDIOVASCULAR SYSTEM	141
<i>ReoPro (LY)</i>	
.BLOOD AND BLOOD FORMING ORGANS	106
<i>Repalyte New Formulation (SW)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	77
<i>Replicare Ultra 66000434 (SN)</i>	
.Repatriation Schedule	1283
<i>Resolve Thrush (EO)</i>	
.Repatriation Schedule	1250
<i>Resonium-A (SW)</i>	
.Repatriation Schedule	1270
<i>Respikast 4 (QA)</i>	
.RESPIRATORY SYSTEM	603
<i>Respikast 5 (QA)</i>	
.RESPIRATORY SYSTEM.....	604
<i>Resprim Forte (AF)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	237
<i>restore O.R.S. (GN)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	77
RETEPLASE	
.BLOOD AND BLOOD FORMING ORGANS.....	110
<i>Retrovir (VI)</i>	
.Section 100.....	749, 1006
<i>Revatio (PF)</i>	
.Section 100.....	727, 982
<i>ReVia (BQ)</i>	
.NERVOUS SYSTEM.....	588
<i>Revlimid (CJ)</i>	
.Section 100.....	905, 907, 908, 1164, 1166
<i>Revolade (GK)</i>	
.Section 100.....	681, 936
<i>Reyataz (BQ)</i>	
.Section 100.....	738, 994
RHAMNUS FRANGULA + STERCULIA	
.ALIMENTARY TRACT AND METABOLISM.....	73
.Palliative Care.....	663
.Repatriation Schedule	1245
<i>Riamet (NV)</i>	
.ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS	591
<i>Riamet 20mg/120mg Dispersible (NV)</i>	
.ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS	592
<i>Ridaura (GH)</i>	
.MUSCULO-SKELETAL SYSTEM	495, 496
RIFABUTIN	
.Section 100.....	737, 993
<i>Rifadin (SW)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	250
RIFAMPICIN	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	249, 250
RIFAXIMIN	
.ALIMENTARY TRACT AND METABOLISM.....	76
RILPIVIRINE	
.Section 100.....	750, 1007
<i>Rilutek (SW)</i>	
.NERVOUS SYSTEM.....	590
RILUZOLE	
.NERVOUS SYSTEM.....	589
<i>Riluzole Sandoz (SZ)</i>	
.NERVOUS SYSTEM.....	590
<i>Rimycin 150 (AF)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	250
<i>Rimycin 300 (AF)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	250
<i>Risedro once a week (QA)</i>	
.MUSCULO-SKELETAL SYSTEM	500
.Repatriation Schedule	1261
RISEDRONATE	

GENERIC/PROPRIETARY INDEX

.MUSCULO-SKELETAL SYSTEM	499, 500	<i>Risperidone-GA (GN)</i>	
.Repatriation Schedule	1261	.NERVOUS SYSTEM	556, 557, 558, 559
RISEDRONATE (&) CALCIUM CARBONATE		<i>Rispernia (ER)</i>	
.MUSCULO-SKELETAL SYSTEM	504	.NERVOUS SYSTEM	556, 557, 558, 559
.Repatriation Schedule	1262	<i>Ritalin 10 (NV)</i>	
RISEDRONATE (&) CALCIUM CARBONATE +		.NERVOUS SYSTEM	575
COLECALCIFEROL		<i>Ritalin LA (NV)</i>	
.MUSCULO-SKELETAL SYSTEM	505	.NERVOUS SYSTEM	574
.Repatriation Schedule	1262	<i>Rithmik 200 (QA)</i>	
<i>Risedronate AN (EA)</i>		.CARDIOVASCULAR SYSTEM	122
.MUSCULO-SKELETAL SYSTEM	500	RITONAVIR	
<i>Risedronate Sandoz (SZ)</i>		.Section 100	741, 997
.MUSCULO-SKELETAL SYSTEM	500	RITUXIMAB	
.Repatriation Schedule	1261	.Section 100	908, 1166
<i>Risedronate-GA (GN)</i>		RIVAROXABAN	
.MUSCULO-SKELETAL SYSTEM	500	.BLOOD AND BLOOD FORMING ORGANS	113, 114,
.Repatriation Schedule	1261	115, 116	
<i>Rispa (QA)</i>		RIVASTIGMINE	
.NERVOUS SYSTEM	556, 557, 558, 559	.NERVOUS SYSTEM	580, 581
<i>Risperdal (JC)</i>		<i>Rivotril (RO)</i>	
.NERVOUS SYSTEM	556, 557, 558, 559	.NERVOUS SYSTEM	528, 529
<i>Risperdal Consta (JC)</i>		.Palliative Care	674
.NERVOUS SYSTEM	558	.Prescriber Bag	56
<i>Risperdal Quicklet (JC)</i>		<i>Rixadone (AF)</i>	
.NERVOUS SYSTEM	556, 557, 558, 559	.NERVOUS SYSTEM	556, 557, 558, 559
<i>Rispericor 0.5 (CR)</i>		RIZATRIPTAN	
.NERVOUS SYSTEM	559	.NERVOUS SYSTEM	525
<i>Rispericor 1 (CR)</i>		<i>Roaccutane (RO)</i>	
.NERVOUS SYSTEM	556, 557	.DERMATOLOGICALS	197, 198
<i>Rispericor 2 (CR)</i>		<i>Rocaltrol (RO)</i>	
.NERVOUS SYSTEM	556, 558	.ALIMENTARY TRACT AND METABOLISM	100
<i>Rispericor 3 (CR)</i>		.MUSCULO-SKELETAL SYSTEM	506
.NERVOUS SYSTEM	556	<i>Rocta 10 (QA)</i>	
<i>Rispericor 4 (CR)</i>		.DERMATOLOGICALS	197
.NERVOUS SYSTEM	556	<i>Rocta 20 (QA)</i>	
RISPERIDONE		.DERMATOLOGICALS	198
.NERVOUS SYSTEM	555, 557, 558, 559	<i>Roferon-A (RO)</i>	
<i>Risperidone Actavis 0.5 (UA)</i>		.ANTINEOPLASTIC AND IMMUNOMODULATING	
.NERVOUS SYSTEM	559	AGENTS	300
<i>Risperidone Actavis 1 (UA)</i>		.Section 100	763, 1021
.NERVOUS SYSTEM	556, 557	ROMIPLOSTIM	
<i>Risperidone Actavis 2 (UA)</i>		.Section 100	681, 936
.NERVOUS SYSTEM	556, 558	ROSIGLITAZONE	
<i>Risperidone Actavis 3 (UA)</i>		.ALIMENTARY TRACT AND METABOLISM	92
.NERVOUS SYSTEM	556	ROSIGLITAZONE + METFORMIN	
<i>Risperidone AN (EA)</i>		.ALIMENTARY TRACT AND METABOLISM	87
.NERVOUS SYSTEM	556, 557, 558, 559	<i>Rostor 10 (DO)</i>	
<i>Risperidone generichealth (GQ)</i>		.CARDIOVASCULAR SYSTEM	164, 165
.NERVOUS SYSTEM	556, 557, 558	<i>Rostor 20 (DO)</i>	
<i>Risperidone GH (GQ)</i>		.CARDIOVASCULAR SYSTEM	164, 165
.NERVOUS SYSTEM	559	<i>Rostor 40 (DO)</i>	
<i>Risperidone Sandoz (SZ)</i>		.CARDIOVASCULAR SYSTEM	164, 165
.NERVOUS SYSTEM	556, 557, 558, 559	<i>Rostor 5 (DO)</i>	
<i>Risperidone-DRLA (RZ)</i>		.CARDIOVASCULAR SYSTEM	164, 166
.NERVOUS SYSTEM	556, 557, 558, 559	ROSUVASTATIN	

GENERIC/PROPRIETARY INDEX

.CARDIOVASCULAR SYSTEM 161, 162, 163, 164
 ROSUVASTATIN (&) EZETIMIBE
 .CARDIOVASCULAR SYSTEM 183, 186
Rosuvastatin Actavis 10 (GN)
 .CARDIOVASCULAR SYSTEM 162, 164, 165
Rosuvastatin Actavis 20 (GN)
 .CARDIOVASCULAR SYSTEM 162, 163, 164, 165
Rosuvastatin Actavis 40 (GN)
 .CARDIOVASCULAR SYSTEM 162, 163, 164, 165
Rosuvastatin Actavis 5 (GN)
 .CARDIOVASCULAR SYSTEM 162, 163, 164, 166
Rosuvastatin AN (EA)
 .CARDIOVASCULAR SYSTEM 164, 165, 166
Rosuvastatin GH (GQ)
 .CARDIOVASCULAR SYSTEM ... 162, 163, 164, 165, 166
Rosuvastatin RBX (RA)
 .CARDIOVASCULAR SYSTEM 164, 165, 166
Rosuvastatin Sandoz (SZ)
 .CARDIOVASCULAR SYSTEM 164, 165, 166
Rosuvastatin-DRLA (RI)
 .CARDIOVASCULAR SYSTEM ... 162, 163, 164, 165, 166
Rosuzet Composite Pack (MK)
 .CARDIOVASCULAR SYSTEM 186, 189
 ROTIGOTINE
 .NERVOUS SYSTEM 542, 543
Roxar 150 (QA)
 .ANTIINFECTIVES FOR SYSTEMIC USE 239
Roxar 300 (QA)
 .ANTIINFECTIVES FOR SYSTEMIC USE 240
Roxet 20 (DO)
 .NERVOUS SYSTEM 568
Roximycin (AF)
 .ANTIINFECTIVES FOR SYSTEMIC USE 239, 240
Roxin (QA)
 .ANTIINFECTIVES FOR SYSTEMIC USE 243
 ROXITHROMYCIN
 .ANTIINFECTIVES FOR SYSTEMIC USE 239
Roxithromycin AN (EA)
 .ANTIINFECTIVES FOR SYSTEMIC USE 239, 240
Roxithromycin GH (GQ)
 .ANTIINFECTIVES FOR SYSTEMIC USE 239, 240
Roxithromycin Sandoz (SZ)
 .ANTIINFECTIVES FOR SYSTEMIC USE 239, 240
Roxithromycin SCP 150 (CR)
 .ANTIINFECTIVES FOR SYSTEMIC USE 239
Roxithromycin SCP 300 (CR)
 .ANTIINFECTIVES FOR SYSTEMIC USE 240
Roxithromycin-GA (GN)
 .ANTIINFECTIVES FOR SYSTEMIC USE 239, 240
Rulide (SW)
 .ANTIINFECTIVES FOR SYSTEMIC USE 239, 240
Rulide D (SW)
 .ANTIINFECTIVES FOR SYSTEMIC USE 240
Rynacrom (SW)
 .Repatriation Schedule 1267

Rythmodan (SW)
 .CARDIOVASCULAR SYSTEM 121

S

S-26 LF (AS)
 .VARIOUS 649
Sabril (SW)
 .NERVOUS SYSTEM 531
Saflutan (MK)
 .SENSORY ORGANS 613
Saizen (SG)
 .Section 100 1203, 1204
Saizen 8 mg click.easy (SG)
 .Section 100 1203
Salazopyrin (PF)
 .ALIMENTARY TRACT AND METABOLISM 80
Salazopyrin-EN (PF)
 .ALIMENTARY TRACT AND METABOLISM 80
 SALBUTAMOL
 .RESPIRATORY SYSTEM 594, 595, 603
Salbutamol Actavis (UA)
 .Prescriber Bag 57, 58
 .RESPIRATORY SYSTEM 595
Salbutamol Sandoz (SZ)
 .Prescriber Bag 57, 58
 .RESPIRATORY SYSTEM 595
Salbutamol-GA (GN)
 .Prescriber Bag 57, 58
 .RESPIRATORY SYSTEM 595
 SALTATONIN
 .SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX
 HORMONES AND INSULINS 221
 SALICYLIC ACID + BENZALKONIUM CHLORIDE + ALCOHOL
 + COAL TAR SOLUTION + POLYOXYETHYLENE ETHERS
 .Repatriation Schedule 1253
 SALMETEROL
 .RESPIRATORY SYSTEM 595
Salofalk (OA)
 .ALIMENTARY TRACT AND METABOLISM 78, 79
Salpraz (AF)
 .ALIMENTARY TRACT AND METABOLISM 65, 66
Sandimmun (NV)
 .Section 100 903, 1162
Sandomigran 0.5 (NV)
 .NERVOUS SYSTEM 527
Sandostatin 0.05 (NV)
 .Section 100 736, 991
Sandostatin 0.1 (NV)
 .Section 100 736, 991
Sandostatin 0.5 (NV)
 .Section 100 736, 991
Sandostatin LAR (NV)
 .Section 100 735, 990
Sandrena (AS)

GENERIC/PROPRIETARY INDEX

.GENITO URINARY SYSTEM AND SEX HORMONES . 207	.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX
<i>Saphris (LU)</i>	HORMONES AND INSULINS 222
.NERVOUS SYSTEM..... 546	<i>SensoCard (PX)</i>
SAPROPTERIN	.VARIOUS..... 630, 631
.ALIMENTARY TRACT AND METABOLISM..... 102	<i>Seprin (QA)</i>
SAQUINAVIR	.ANTIINFECTIVES FOR SYSTEMIC USE..... 237
.Section 100 741, 997	<i>Seprin Forte (QA)</i>
<i>Savacol Mouth and Throat Rinse (OM)</i>	.ANTIINFECTIVES FOR SYSTEMIC USE..... 237
.Repatriation Schedule 1244	<i>Serenace (QA)</i>
SAXAGLIPTIN	.NERVOUS SYSTEM..... 544
.ALIMENTARY TRACT AND METABOLISM..... 94	.Prescriber Bag 56
SAXAGLIPTIN + METFORMIN	<i>Serepax (QA)</i>
.ALIMENTARY TRACT AND METABOLISM..... 87	.NERVOUS SYSTEM..... 561
<i>Sculptura (GA)</i>	.Palliative Care..... 675
.VARIOUS..... 628, 629	<i>Seretide Accuhaler 100/50 (GK)</i>
<i>Scytera (RZ)</i>	.RESPIRATORY SYSTEM..... 597
.DERMATOLOGICALS..... 193	<i>Seretide Accuhaler 250/50 (GK)</i>
<i>Seaze 100 (QA)</i>	.RESPIRATORY SYSTEM..... 598
.NERVOUS SYSTEM..... 534	<i>Seretide Accuhaler 500/50 (GK)</i>
<i>Seaze 200 (QA)</i>	.RESPIRATORY SYSTEM..... 598
.NERVOUS SYSTEM..... 534	<i>Seretide MDI 125/25 (GK)</i>
<i>Seaze 25 (QA)</i>	.RESPIRATORY SYSTEM..... 598
.NERVOUS SYSTEM..... 534	<i>Seretide MDI 250/25 (GK)</i>
<i>Seaze 5 (QA)</i>	.RESPIRATORY SYSTEM..... 598
.NERVOUS SYSTEM..... 534	<i>Seretide MDI 50/25 (GK)</i>
<i>Seaze 50 (QA)</i>	.RESPIRATORY SYSTEM..... 598
.NERVOUS SYSTEM..... 535	<i>Serevent Accuhaler (GK)</i>
<i>Sebifin 250 (RA)</i>	.RESPIRATORY SYSTEM..... 595
.DERMATOLOGICALS..... 193	<i>Seronia 100 (QA)</i>
<i>SebiRinse (EO)</i>	.NERVOUS SYSTEM..... 552
.Repatriation Schedule 1254	<i>Seronia 200 (QA)</i>
<i>Sebitar (EO)</i>	.NERVOUS SYSTEM..... 553
.Repatriation Schedule 1253	<i>Seronia 25 (QA)</i>
<i>Sebivo (NV)</i>	.NERVOUS SYSTEM..... 554
.Section 100 747, 1004	<i>Seronia 300 (QA)</i>
<i>Sebizole (GN)</i>	.NERVOUS SYSTEM..... 553
.Repatriation Schedule 1250	<i>Serophene (SG)</i>
<i>seebri breezhaler (NV)</i>	.GENITO URINARY SYSTEM AND SEX HORMONES . 210
.RESPIRATORY SYSTEM 601	<i>Seroquel (AP)</i>
SELEGILINE	.NERVOUS SYSTEM..... 552, 553, 554
.NERVOUS SYSTEM..... 543	<i>Seroquel XR (AP)</i>
SELENIUM SULFIDE	.NERVOUS SYSTEM..... 552, 553
.Repatriation Schedule 1253	<i>Sertra 100 (QA)</i>
<i>Selgene (AF)</i>	.NERVOUS SYSTEM..... 568
.NERVOUS SYSTEM..... 543	<i>Sertra 50 (QA)</i>
<i>Selsun (DQ)</i>	.NERVOUS SYSTEM..... 568
.Repatriation Schedule 1253	<i>Sertracor 100 (CR)</i>
<i>Senna-Gen (PP)</i>	.NERVOUS SYSTEM..... 568
.Repatriation Schedule 1245	<i>Sertracor 50 (CR)</i>
SENNOSIDE B	.NERVOUS SYSTEM..... 568
.Repatriation Schedule 1245	SERTRALINE
<i>Senokot (RC)</i>	.NERVOUS SYSTEM..... 568, 569
.Repatriation Schedule 1245	<i>Sertraline Actavis (UA)</i>
<i>Sensipar (AN)</i>	.NERVOUS SYSTEM..... 568, 569
.Section 100 736, 991	<i>Sertraline AN (EA)</i>

GENERIC/PROPRIETARY INDEX

.NERVOUS SYSTEM.....	568, 569
<i>Sertraline generichealth (GQ)</i>	
.NERVOUS SYSTEM.....	568
<i>Sertraline Sandoz (SZ)</i>	
.NERVOUS SYSTEM.....	568
<i>Sertraline-DRLA (RZ)</i>	
.NERVOUS SYSTEM.....	568
<i>Setopress 3505 (MH)</i>	
.Repatriation Schedule	1273
<i>Setrona (RA)</i>	
.NERVOUS SYSTEM.....	568
SEVELAMER	
.Section 100	934, 1197
.VARIOUS.....	627
<i>Sevikar 20/5 (MK)</i>	
.CARDIOVASCULAR SYSTEM	152
<i>Sevikar 40/10 (MK)</i>	
.CARDIOVASCULAR SYSTEM	152
<i>Sevikar 40/5 (MK)</i>	
.CARDIOVASCULAR SYSTEM	152
<i>Sevikar HCT 20/5/12.5 (MK)</i>	
.CARDIOVASCULAR SYSTEM	153
<i>Sevikar HCT 40/10/12.5 (MK)</i>	
.CARDIOVASCULAR SYSTEM	153
<i>Sevikar HCT 40/10/25 (MK)</i>	
.CARDIOVASCULAR SYSTEM	153
<i>Sevikar HCT 40/5/12.5 (MK)</i>	
.CARDIOVASCULAR SYSTEM	153
<i>Sevikar HCT 40/5/25 (MK)</i>	
.CARDIOVASCULAR SYSTEM	153
<i>Sevredol (MF)</i>	
.NERVOUS SYSTEM.....	514
.Palliative Care	671
<i>Shilova 500 (DO)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	254
<i>Sical (AF)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	100
.MUSCULO-SKELETAL SYSTEM	506
<i>Sifrol (BY)</i>	
.NERVOUS SYSTEM.....	541, 542
<i>Sifrol ER (BY)</i>	
.NERVOUS SYSTEM.....	542
<i>Sigmacort (QA)</i>	
.DERMATOLOGICALS.....	195
<i>Sigmaxin (FM)</i>	
.CARDIOVASCULAR SYSTEM	121
<i>Sigmaxin-PG (FM)</i>	
.CARDIOVASCULAR SYSTEM	121
<i>Silaran (RA)</i>	
.Repatriation Schedule	1256
SILDENAFIL	
.Repatriation Schedule	1256
.Section 100	721, 976
<i>Sildenafil AN PHT 20 (EA)</i>	
.Section 100	727, 982
<i>Sildenafil GH (GQ)</i>	
.Repatriation Schedule	1256
<i>Sildenafil Sandoz PHT 20 (SZ)</i>	
.Section 100.....	727, 982
<i>SILDENAFIL-DRx (RZ)</i>	
.Section 100.....	727, 982
<i>Silic 15 (EO)</i>	
.Repatriation Schedule	1251
SIMEPREVIR	
.Section 100.....	741, 998
<i>Simipex 0.125 (QA)</i>	
.NERVOUS SYSTEM.....	541
<i>Simipex 0.25 (QA)</i>	
.NERVOUS SYSTEM.....	541
<i>Simipex 1 (QA)</i>	
.NERVOUS SYSTEM.....	541
<i>Simplotan (FZ)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	245
<i>Simponi (JC)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	463, 466, 471, 474, 477, 480
<i>Simpral (AF)</i>	
.NERVOUS SYSTEM.....	541
<i>Simvacor 10 (CR)</i>	
.CARDIOVASCULAR SYSTEM	166, 167
<i>Simvacor 20 (CR)</i>	
.CARDIOVASCULAR SYSTEM	166, 168
<i>Simvacor 40 (CR)</i>	
.CARDIOVASCULAR SYSTEM	166, 168
<i>Simvacor 80 (CR)</i>	
.CARDIOVASCULAR SYSTEM	167, 168
<i>Simvar 10 (QA)</i>	
.CARDIOVASCULAR SYSTEM	166, 167
<i>Simvar 20 (QA)</i>	
.CARDIOVASCULAR SYSTEM	166, 168
<i>Simvar 40 (QA)</i>	
.CARDIOVASCULAR SYSTEM	166, 168
<i>Simvar 80 (QA)</i>	
.CARDIOVASCULAR SYSTEM	167, 168
SIMVASTATIN	
.CARDIOVASCULAR SYSTEM	166, 167
<i>Simvastatin AN (EA)</i>	
.CARDIOVASCULAR SYSTEM	166, 167, 168
<i>Simvastatin generichealth (GQ)</i>	
.CARDIOVASCULAR SYSTEM	166, 167, 168
<i>Simvastatin Sandoz (SZ)</i>	
.CARDIOVASCULAR SYSTEM	166, 167, 168
<i>Simvastatin-DP (UA)</i>	
.CARDIOVASCULAR SYSTEM	166, 167, 168
<i>Simvastatin-DRLA (RZ)</i>	
.CARDIOVASCULAR SYSTEM	166, 167, 168
<i>Simvastatin-GA 10 (GN)</i>	
.CARDIOVASCULAR SYSTEM	166, 167
<i>Simvastatin-GA 20 (GN)</i>	
.CARDIOVASCULAR SYSTEM	166, 168

GENERIC/PROPRIETARY INDEX

<i>Simvastatin-GA 40 (GN)</i>		
.CARDIOVASCULAR SYSTEM	167, 168	
<i>Simvastatin-GA 80 (GN)</i>		
.CARDIOVASCULAR SYSTEM	167, 168	
<i>Sinemet (MK)</i>		
.NERVOUS SYSTEM	539	
<i>Sinemet 100/25 (MK)</i>		
.NERVOUS SYSTEM	539	
<i>Sinemet CR (MK)</i>		
.NERVOUS SYSTEM	540	
<i>Sinequan (PF)</i>		
.NERVOUS SYSTEM	564	
<i>Singulair (MK)</i>		
.RESPIRATORY SYSTEM	603, 604	
SIROLIMUS		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	316	
.Section 100	803, 1061	
SITAGLIPTIN		
.ALIMENTARY TRACT AND METABOLISM	95	
SITAGLIPTIN + METFORMIN		
.ALIMENTARY TRACT AND METABOLISM	88	
<i>Skelid (SW)</i>		
.MUSCULO-SKELETAL SYSTEM	501	
SKIN EMOLLIENT		
.Repatriation Schedule	1251	
<i>Slow-K (NV)</i>		
.ALIMENTARY TRACT AND METABOLISM	101	
<i>Sno-Pro (SB)</i>		
.VARIOUS	659	
<i>Sodibic (AS)</i>		
.GENITO URINARY SYSTEM AND SEX HORMONES .	212	
SODIUM CHLORIDE		
.BLOOD AND BLOOD FORMING ORGANS	120	
.Repatriation Schedule	1248	
SODIUM CHLORIDE + GLUCOSE		
.BLOOD AND BLOOD FORMING ORGANS	120	
SODIUM CHLORIDE + POTASSIUM CHLORIDE + GLUCOSE		
MONOHYDRATE + CITRATE		
.ALIMENTARY TRACT AND METABOLISM	77	
SODIUM GLUCONATE + SODIUM CHLORIDE +		
POTASSIUM CHLORIDE + MAGNESIUM CHLORIDE +		
SODIUM ACETATE TRIHYDRATE + GLUCOSE		
.BLOOD AND BLOOD FORMING ORGANS	120	
SODIUM HYALURONATE		
.SENSORY ORGANS	623, 624	
<i>Sodium Valproate Sandoz (SZ)</i>		
.NERVOUS SYSTEM	530, 531	
<i>Sofflux (GN)</i>		
.Repatriation Schedule	1244	
<i>Sofradex (SW)</i>		
.SENSORY ORGANS	624	
<i>Soframycin (SW)</i>		
.SENSORY ORGANS	625	
<i>Solaraze 3% Gel (CS)</i>		
.Repatriation Schedule	1254	
<i>Solavert (QA)</i>		
.CARDIOVASCULAR SYSTEM	122	
<i>Solian 100 (SW)</i>		
.NERVOUS SYSTEM	554	
<i>Solian 200 (SW)</i>		
.NERVOUS SYSTEM	554	
<i>Solian 400 (SW)</i>		
.NERVOUS SYSTEM	554	
<i>Solian Solution (SW)</i>		
.NERVOUS SYSTEM	554	
<i>Soliris (XI)</i>		
.Section 100	792, 793, 801, 1057, 1058, 1059	
<i>Solone (IA)</i>		
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX		
HORMONES AND INSULINS	218	
<i>SoloSite Gel 36361338 (SN)</i>		
.Repatriation Schedule	1284	
<i>Solprin (RC)</i>		
.BLOOD AND BLOOD FORMING ORGANS	106	
.NERVOUS SYSTEM	523	
<i>Solu-Cortef (PF)</i>		
.Prescriber Bag	56	
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX		
HORMONES AND INSULINS	217	
<i>Solugel 10336 (JJ)</i>		
.Repatriation Schedule	1284	
<i>Solu-Medrol (PF)</i>		
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX		
HORMONES AND INSULINS	217	
<i>Somac (NQ)</i>		
.ALIMENTARY TRACT AND METABOLISM	65, 66	
SOMATROPIN		
.Section 100	1203, 1204	
<i>Somatuline Autogel (IS)</i>		
.Section 100	734, 989	
<i>Somatuline LA (IS)</i>		
.Section 100	735, 990	
<i>Sone (IA)</i>		
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX		
HORMONES AND INSULINS	218	
SORAFENIB		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	287, 288	
<i>Sorbact Absorption Dressing S98222 (QL)</i>		
.Repatriation Schedule	1284	
<i>Sorbact Foam Dressing S98310 (QL)</i>		
.Repatriation Schedule	1284	
<i>Sorbact Ribbon Gauze S98118 (QL)</i>		
.Repatriation Schedule	1284	
<i>Sorbact Ribbon Gauze S98120 (QL)</i>		
.Repatriation Schedule	1284	
SORBITOL + CITRATE + LAURYL SULFOACETATE SODIUM		
.ALIMENTARY TRACT AND METABOLISM	75	
.Palliative Care	665	

GENERIC/PROPRIETARY INDEX

.Repatriation Schedule.....	1245	.ANTINEOPLASTIC AND IMMUNOMODULATING	
<i>Sorbsan 1410 (UM)</i>		AGENTS	485, 488
.Repatriation Schedule.....	1277	<i>Stelax 10 (QA)</i>	
<i>Sorbsan 1411 (UM)</i>		.MUSCULO-SKELETAL SYSTEM	496
.Repatriation Schedule.....	1277	<i>Stelax 25 (QA)</i>	
<i>Sotacor (FM)</i>		.MUSCULO-SKELETAL SYSTEM	496
.CARDIOVASCULAR SYSTEM	122	<i>Stelazine (GH)</i>	
SOTALOL		.NERVOUS SYSTEM.....	544
.CARDIOVASCULAR SYSTEM	122	<i>Stemetil (SW)</i>	
<i>Sotalol Sandoz (SZ)</i>		.ALIMENTARY TRACT AND METABOLISM.....	72
.CARDIOVASCULAR SYSTEM	122	.Prescriber Bag	57
SOY LECITHIN + TOCOPHEROLS + VITAMIN A		<i>Stemzine (AV)</i>	
.SENSORY ORGANS.....	624	.ALIMENTARY TRACT AND METABOLISM.....	72
SOY PROTEIN AND FAT FORMULA WITH VITAMINS AND		<i>Steripaste 3610 (MH)</i>	
MINERALS CARBOHYDRATE FREE		.Repatriation Schedule	1276
.VARIOUS.....	658	<i>Stieprox Liquid (GK)</i>	
<i>Sozol (QA)</i>		.Repatriation Schedule	1250
.ALIMENTARY TRACT AND METABOLISM.....	65, 66	<i>Stocrin (MK)</i>	
<i>Span-K (AS)</i>		.Section 100.....	749, 750, 1006
.ALIMENTARY TRACT AND METABOLISM.....	101	<i>Strattera (LY)</i>	
<i>Spiractin 100 (AF)</i>		.NERVOUS SYSTEM.....	574
.CARDIOVASCULAR SYSTEM	127	<i>Stribild (GI)</i>	
<i>Spiractin 25 (AF)</i>		.Section 100.....	754, 1011
.CARDIOVASCULAR SYSTEM	127	<i>Stromectol (MK)</i>	
<i>Spiriva (BY)</i>		.ANTIPARASITIC PRODUCTS, INSECTICIDES AND	
.RESPIRATORY SYSTEM	602	REPELLENTS	593
SPIRONOLACTONE		STRONTIUM	
.CARDIOVASCULAR SYSTEM	127	.MUSCULO-SKELETAL SYSTEM	508
<i>Sporanox (JC)</i>		<i>Suboxone Film 2/0.5 (RC)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	247	.Section 100.....	1208
<i>Spren 100 (QA)</i>		<i>Suboxone Film 8/2 (RC)</i>	
.BLOOD AND BLOOD FORMING ORGANS	106	.Section 100.....	1208
<i>Sprycel (BQ)</i>		<i>Subutex (RC)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING		.Section 100.....	1208
AGENTS	262, 264, 265	SUCRALFATE	
<i>Stalevo 100/25/200mg (NV)</i>		.ALIMENTARY TRACT AND METABOLISM.....	67
.NERVOUS SYSTEM.....	540	SUCROFERRIC OXYHYDROXIDE	
<i>Stalevo 125/31.25/200mg (NV)</i>		.Section 100.....	934, 1197
.NERVOUS SYSTEM.....	540	.VARIOUS.....	627
<i>Stalevo 150/37.5/200mg (NV)</i>		SULFADIAZINE SILVER	
.NERVOUS SYSTEM.....	540	.DERMATOLOGICALS	195
<i>Stalevo 200/50/200mg (NV)</i>		SULFASALAZINE	
.NERVOUS SYSTEM.....	540	.ALIMENTARY TRACT AND METABOLISM.....	80
<i>Stalevo 50/12.5/200mg (NV)</i>		<i>Sulprix (AF)</i>	
.NERVOUS SYSTEM.....	540	.NERVOUS SYSTEM.....	554
<i>Stalevo 75/18.75/200mg (NV)</i>		SULTHIAME	
.NERVOUS SYSTEM.....	540	.NERVOUS SYSTEM.....	536
<i>Staphylex 250 (AF)</i>		<i>Sumagran Aspen 50 (AS)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	228	.NERVOUS SYSTEM.....	526
<i>Staphylex 500 (AF)</i>		<i>Sumatab (AF)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	229	.NERVOUS SYSTEM.....	526
STAVUDINE		<i>Sumatran (QA)</i>	
.Section 100	747, 1003	.NERVOUS SYSTEM.....	526
<i>Stelara (JC)</i>		SUMATRIPTAN	
		.NERVOUS SYSTEM.....	526

GENERIC/PROPRIETARY INDEX

<i>Sumatriptan AN (EA)</i>		<i>.RESPIRATORY SYSTEM</i> 603, 604
<i>.NERVOUS SYSTEM</i>	526	<i>Tacidine (AF)</i>
<i>Sumatriptan generichealth (GQ)</i>		<i>.ALIMENTARY TRACT AND METABOLISM</i> 61
<i>.NERVOUS SYSTEM</i>	526	TACROLIMUS
<i>Sumatriptan RBX (RA)</i>		<i>.ANTINEOPLASTIC AND IMMUNOMODULATING</i>
<i>.NERVOUS SYSTEM</i>	527	AGENTS 488
<i>Sumatriptan Sandoz (SZ)</i>		<i>.Section 100</i> 903, 1162
<i>.NERVOUS SYSTEM</i>	526, 527	<i>Tacrolimus Sandoz (SZ)</i>
<i>Sumatriptan-GA (GN)</i>		<i>.ANTINEOPLASTIC AND IMMUNOMODULATING</i>
<i>.NERVOUS SYSTEM</i>	526	AGENTS 488
SUNITINIB		<i>.Section 100</i> 904, 1162
<i>.ANTINEOPLASTIC AND IMMUNOMODULATING</i>		TADALAFIL
AGENTS 288, 289, 290		<i>.Repatriation Schedule</i> 1257
SUNSCREENS		<i>.Section 100</i> 727, 982
<i>.Repatriation Schedule</i>	1251	<i>Tafinlar (GK)</i>
<i>Sunsense Sensitive SPF 50+ (EO)</i>		<i>.ANTINEOPLASTIC AND IMMUNOMODULATING</i>
<i>.Repatriation Schedule</i>	1251	AGENTS 260
<i>Sunsense Ultra SPF 50+ (EO)</i>		TAFLUPROST
<i>.Repatriation Schedule</i>	1251	<i>.SENSORY ORGANS</i> 613
<i>Surepress 650947 (CC)</i>		<i>Talam (QA)</i>
<i>.Repatriation Schedule</i>	1273	<i>.NERVOUS SYSTEM</i> 564
<i>Surepress 650948 (CC)</i>		<i>Tamate (AF)</i>
<i>.Repatriation Schedule</i>	1273	<i>.NERVOUS SYSTEM</i> 537, 538
<i>Sutent (PF)</i>		<i>Tambocor (IA)</i>
<i>.ANTINEOPLASTIC AND IMMUNOMODULATING</i>		<i>.CARDIOVASCULAR SYSTEM</i> 121
AGENTS 289, 290, 291		<i>Tamosin (QA)</i>
<i>Symbicort Rapihaler 100/3 (AP)</i>		<i>.ANTINEOPLASTIC AND IMMUNOMODULATING</i>
<i>.RESPIRATORY SYSTEM</i> 595		AGENTS 294
<i>Symbicort Rapihaler 200/6 (AP)</i>		<i>Tamoxen 20 mg (GN)</i>
<i>.RESPIRATORY SYSTEM</i> 596		<i>.ANTINEOPLASTIC AND IMMUNOMODULATING</i>
<i>Symbicort Rapihaler 50/3 (AP)</i>		AGENTS 294
<i>.RESPIRATORY SYSTEM</i> 595		TAMOXIFEN
<i>Symbicort Turbuhaler 100/6 (AP)</i>		<i>.ANTINEOPLASTIC AND IMMUNOMODULATING</i>
<i>.RESPIRATORY SYSTEM</i> 596		AGENTS 294
<i>Symbicort Turbuhaler 200/6 (AP)</i>		<i>Tamoxifen Sandoz (SZ)</i>
<i>.RESPIRATORY SYSTEM</i> 596		<i>.ANTINEOPLASTIC AND IMMUNOMODULATING</i>
<i>Symbicort Turbuhaler 400/12 (AP)</i>		AGENTS 294
<i>.RESPIRATORY SYSTEM</i> 597		<i>Tamsil (QA)</i>
<i>Symmetrel 100 (NV)</i>		<i>.DERMATOLOGICALS</i> 193
<i>.NERVOUS SYSTEM</i>	540	<i>.Repatriation Schedule</i> 1251
<i>Synacthen Depot 1 mg/1 mL (NV)</i>		TAMSULOSIN
<i>.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX</i>		<i>.Repatriation Schedule</i> 1257
<i>HORMONES AND INSULINS</i>	214	<i>Tamsulosin Sandoz SR (SZ)</i>
<i>Synarel (PF)</i>		<i>.Repatriation Schedule</i> 1257
<i>.Section 100</i> 1206		TAPE NON WOVEN RETENTION POLYACRYLATE
<i>.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX</i>		<i>.Repatriation Schedule</i> 1286
<i>HORMONES AND INSULINS</i>	215	TAPE PLASTER ADHESIVE ELASTIC
<i>Syquet (AF)</i>		<i>.Repatriation Schedule</i> 1286
<i>.NERVOUS SYSTEM</i>	552, 553, 554	TAPE PLASTER ADHESIVE HYPOALLERGENIC
<i>Systane (AQ)</i>		<i>.Repatriation Schedule</i> 1286, 1287
<i>.SENSORY ORGANS</i>	622, 623	TAPE PLASTER ADHESIVE WITH SILICONE
		<i>.Repatriation Schedule</i> 1287
		TAPENTADOL
		<i>.NERVOUS SYSTEM</i> 520

T

T Lukast (AF)

GENERIC/PROPRIETARY INDEX

TAR + CADE OIL + COAL TAR + ARACHIS OIL EXTRACT OF COAL TAR	
.Repatriation Schedule	1253
<i>Tarceva (RO)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	265, 266
<i>Targin 10/5mg (MF)</i>	
.NERVOUS SYSTEM	516
<i>Targin 20/10mg (MF)</i>	
.NERVOUS SYSTEM	516
<i>Targin 40/20mg (MF)</i>	
.NERVOUS SYSTEM	516
<i>Targin 5/2.5mg (MF)</i>	
.NERVOUS SYSTEM	516
<i>Tarka 2/180 (GO)</i>	
.CARDIOVASCULAR SYSTEM	143
<i>Tarka 4/240 (GO)</i>	
.CARDIOVASCULAR SYSTEM	143
<i>Tasigna (NV)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	281, 283
<i>Tazac (AS)</i>	
.ALIMENTARY TRACT AND METABOLISM	61
<i>Tears Naturelle (AQ)</i>	
.SENSORY ORGANS	620
<i>tearsagain (RB)</i>	
.SENSORY ORGANS	624
<i>Tecfidera (BD)</i>	
.NERVOUS SYSTEM	588, 589
<i>Tegaderm Transparent 1628 (MM)</i>	
.Repatriation Schedule	1278
<i>Tegaderm Transparent Island 3582 (MM)</i>	
.Repatriation Schedule	1278
<i>Tegaderm Transparent Island 3586 (MM)</i>	
.Repatriation Schedule	1278
<i>Tegretol 100 (NV)</i>	
.NERVOUS SYSTEM	529
<i>Tegretol 200 (NV)</i>	
.NERVOUS SYSTEM	529
<i>Tegretol CR 200 (NV)</i>	
.NERVOUS SYSTEM	529, 530
<i>Tegretol CR 400 (NV)</i>	
.NERVOUS SYSTEM	529, 530
<i>Tegretol Liquid (NV)</i>	
.NERVOUS SYSTEM	529, 530
TELAPREVIR	
.Section 100	743, 999
TELBIVUDINE	
.Section 100	747, 1004
<i>Telfa 1970C (KE)</i>	
.Repatriation Schedule	1285
<i>Telfa 2140C (KE)</i>	
.Repatriation Schedule	1285
<i>Telfa 7650C (KE)</i>	
.Repatriation Schedule	1285
<i>Telfa 8252F (KE)</i>	
.Repatriation Schedule	1274
<i>Telfa 8253F (KE)</i>	
.Repatriation Schedule	1274
<i>Telfa 8254F (KE)</i>	
.Repatriation Schedule	1274
<i>Telfast (SW)</i>	
.Repatriation Schedule	1268
<i>Telfast 120 (SW)</i>	
.Repatriation Schedule	1268
<i>Telmigen (GN)</i>	
.CARDIOVASCULAR SYSTEM	146
<i>Telmigen HCT 40/12.5 (GN)</i>	
.CARDIOVASCULAR SYSTEM	150
<i>Telmigen HCT 80/12.5 (GN)</i>	
.CARDIOVASCULAR SYSTEM	150
<i>Telmigen HCT 80/25 (GN)</i>	
.CARDIOVASCULAR SYSTEM	151
TELMISARTAN	
.CARDIOVASCULAR SYSTEM	146
TELMISARTAN + AMLODIPINE	
.CARDIOVASCULAR SYSTEM	152
TELMISARTAN + HYDROCHLOROTHIAZIDE	
.CARDIOVASCULAR SYSTEM	150
<i>Telmisartan AN (EA)</i>	
.CARDIOVASCULAR SYSTEM	146
<i>Telmisartan GH (GQ)</i>	
.CARDIOVASCULAR SYSTEM	146
<i>Telmisartan HCT GH 40/12.5 (GQ)</i>	
.CARDIOVASCULAR SYSTEM	150
<i>Telmisartan HCT GH 80/12.5 (GQ)</i>	
.CARDIOVASCULAR SYSTEM	151
<i>Telmisartan HCT GH 80/25 (GQ)</i>	
.CARDIOVASCULAR SYSTEM	151
<i>Telmisartan HCTZ AN 40/12.5 (EA)</i>	
.CARDIOVASCULAR SYSTEM	150
<i>Telmisartan HCTZ AN 80/12.5 (EA)</i>	
.CARDIOVASCULAR SYSTEM	151
<i>Telmisartan HCTZ AN 80/25 (EA)</i>	
.CARDIOVASCULAR SYSTEM	151
<i>Telmisartan RBX (RA)</i>	
.CARDIOVASCULAR SYSTEM	146
<i>Telmisartan Sandoz (SZ)</i>	
.CARDIOVASCULAR SYSTEM	146, 147
<i>Telmisartan/HCT Sandoz (SZ)</i>	
.CARDIOVASCULAR SYSTEM	150, 151
<i>Telmisartan-DRLA (RZ)</i>	
.CARDIOVASCULAR SYSTEM	146
<i>Teltartan (QA)</i>	
.CARDIOVASCULAR SYSTEM	146, 147
<i>Teltartan HCT 40/12.5 (QA)</i>	
.CARDIOVASCULAR SYSTEM	150
<i>Teltartan HCT 80/12.5 (QA)</i>	
.CARDIOVASCULAR SYSTEM	151
<i>Teltartan HCT 80/25 (QA)</i>	

GENERIC/PROPRIETARY INDEX

.CARDIOVASCULAR SYSTEM	151	TENOFOVIR + EMTRICITABINE + ELVITEGRAVIR +	
<i>Telzir (VI)</i>		COBICISTAT	
.Section 100	740, 997	.Section 100.....	754, 1011
<i>Temaze (AF)</i>		<i>Tenolten 50 (DO)</i>	
.NERVOUS SYSTEM.....	562	.CARDIOVASCULAR SYSTEM	128
.Palliative Care	676	<i>Tenopt (QA)</i>	
TEMAZEPAM		.SENSORY ORGANS.....	611
.NERVOUS SYSTEM.....	562	<i>Tenormin (AP)</i>	
.Palliative Care	676	.CARDIOVASCULAR SYSTEM	129
<i>Temizole 100 (QA)</i>		<i>Tensig (QA)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING		.CARDIOVASCULAR SYSTEM	128
AGENTS	256, 257	<i>Tensocrepe 36300501 (BV)</i>	
<i>Temizole 140 (QA)</i>		.Repatriation Schedule	1274
.ANTINEOPLASTIC AND IMMUNOMODULATING		<i>Tensocrepe 36301001 (BV)</i>	
AGENTS	256, 257	.Repatriation Schedule	1274
<i>Temizole 20 (QA)</i>		<i>Tensocrepe 36307501 (BV)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING		.Repatriation Schedule	1274
AGENTS	256, 257	<i>Tensoress 71723-00 (BV)</i>	
<i>Temizole 250 (QA)</i>		.Repatriation Schedule	1273
.ANTINEOPLASTIC AND IMMUNOMODULATING		TERAZOSIN	
AGENTS	257	.Repatriation Schedule	1257
<i>Temizole 5 (QA)</i>		TERBINAFINE	
.ANTINEOPLASTIC AND IMMUNOMODULATING		.DERMATOLOGICALS	192, 193
AGENTS	257	.Repatriation Schedule	1250
<i>Temodal (MK)</i>		<i>Terbinafine Actavis (VN)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING		.DERMATOLOGICALS	193
AGENTS	256, 257	<i>Terbinafine AN (EA)</i>	
TEMOZOLOMIDE		.DERMATOLOGICALS	193
.ANTINEOPLASTIC AND IMMUNOMODULATING		<i>Terbinafine GH (GQ)</i>	
AGENTS	256, 257	.DERMATOLOGICALS	193
<i>Temozolomide Alphapharm (AF)</i>		.Repatriation Schedule	1251
.ANTINEOPLASTIC AND IMMUNOMODULATING		<i>Terbinafine Sandoz (SZ)</i>	
AGENTS	256, 257	.DERMATOLOGICALS	193
<i>Temozolomide AN (EA)</i>		.Repatriation Schedule	1251
.ANTINEOPLASTIC AND IMMUNOMODULATING		<i>Terbinafine-DRLA (RZ)</i>	
AGENTS	256, 257, 258	.DERMATOLOGICALS	193
<i>Temotabs (FM)</i>		TERBUTALINE	
.NERVOUS SYSTEM.....	562	.RESPIRATORY SYSTEM.....	595, 603
.Palliative Care	676	TERIFLUNOMIDE	
<i>Tenaxil SR (QA)</i>		.ANTINEOPLASTIC AND IMMUNOMODULATING	
.CARDIOVASCULAR SYSTEM	126	AGENTS	316
<i>TenderWet 24 Active 609210 (HR)</i>		<i>Teril (AF)</i>	
.Repatriation Schedule	1281	.NERVOUS SYSTEM.....	529, 530
<i>TenderWet 24 Active 609213 (HR)</i>		TERIPARATIDE	
.Repatriation Schedule	1281	.MUSCULO-SKELETAL SYSTEM	509
<i>TenderWet Active Cavity 609272 (HR)</i>		.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX	
.Repatriation Schedule	1281	HORMONES AND INSULINS	220
TENECTEPLASE		<i>Terry White Chemists Aciclovir (TW)</i>	
.BLOOD AND BLOOD FORMING ORGANS	110	.ANTIINFECTIVES FOR SYSTEMIC USE	250
TENOFOVIR		<i>Terry White Chemists Alendronate 70mg (TW)</i>	
.Section 100	747, 1004	.MUSCULO-SKELETAL SYSTEM	498
TENOFOVIR + EMTRICITABINE		<i>Terry White Chemists Allopurinol (TW)</i>	
.Section 100	753, 1010	.MUSCULO-SKELETAL SYSTEM	497
TENOFOVIR + EMTRICITABINE + EFAVIRENZ		<i>Terry White Chemists Alprazolam (TW)</i>	
.Section 100	753, 1011	.NERVOUS SYSTEM.....	560

GENERIC/PROPRIETARY INDEX

<i>Terry White Chemists Amiodarone (TW)</i>	
.CARDIOVASCULAR SYSTEM	122
<i>Terry White Chemists Amitriptyline (TW)</i>	
.NERVOUS SYSTEM.....	563
<i>Terry White Chemists Amlodipine (TW)</i>	
.CARDIOVASCULAR SYSTEM	132
<i>Terry White Chemists Amlodipine/Atorvastatin 10/10 (TW)</i>	
.CARDIOVASCULAR SYSTEM	190
<i>Terry White Chemists Amlodipine/Atorvastatin 10/20 (TW)</i>	
.CARDIOVASCULAR SYSTEM	190
<i>Terry White Chemists Amlodipine/Atorvastatin 10/40 (TW)</i>	
.CARDIOVASCULAR SYSTEM	190
<i>Terry White Chemists Amlodipine/Atorvastatin 10/80 (TW)</i>	
.CARDIOVASCULAR SYSTEM	190
<i>Terry White Chemists Amlodipine/Atorvastatin 5/10 (TW)</i>	
.CARDIOVASCULAR SYSTEM	190
<i>Terry White Chemists Amlodipine/Atorvastatin 5/20 (TW)</i>	
.CARDIOVASCULAR SYSTEM	191
<i>Terry White Chemists Amlodipine/Atorvastatin 5/40 (TW)</i>	
.CARDIOVASCULAR SYSTEM	191
<i>Terry White Chemists Amlodipine/Atorvastatin 5/80 (TW)</i>	
.CARDIOVASCULAR SYSTEM	191
<i>Terry White Chemists Amoxicillin (TW)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	225, 226
<i>Terry White Chemists Amoxicillin and Clavulanic Acid (TW)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	230
<i>Terry White Chemists Anastrozole (TW)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	297
<i>Terry White Chemists Atenolol (TW)</i>	
.CARDIOVASCULAR SYSTEM	128
<i>Terry White Chemists Atorvastatin (TW)</i>	
.CARDIOVASCULAR SYSTEM	156, 157, 158, 159
<i>Terry White Chemists Azithromycin (TW)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	238
.Repatriation Schedule	1259
.SENSORY ORGANS.....	605
<i>Terry White Chemists Baclofen (TW)</i>	
.MUSCULO-SKELETAL SYSTEM	496
<i>Terry White Chemists Bisoprolol (TW)</i>	
.CARDIOVASCULAR SYSTEM	129
<i>Terry White Chemists Candesartan (TW)</i>	
.CARDIOVASCULAR SYSTEM	144
<i>Terry White Chemists Candesartan HCTZ 16/12.5 (TW)</i>	
.CARDIOVASCULAR SYSTEM	147
<i>Terry White Chemists Candesartan HCTZ 32/12.5 (TW)</i>	
.CARDIOVASCULAR SYSTEM	148
<i>Terry White Chemists Candesartan HCTZ 32/25 (TW)</i>	
.CARDIOVASCULAR SYSTEM	148
<i>Terry White Chemists Carvedilol 12.5 mg (TW)</i>	
.CARDIOVASCULAR SYSTEM	131
<i>Terry White Chemists Carvedilol 25 mg (TW)</i>	
.CARDIOVASCULAR SYSTEM	131
<i>Terry White Chemists Carvedilol 3.125 mg (TW)</i>	
.CARDIOVASCULAR SYSTEM	131
<i>Terry White Chemists Carvedilol 6.25 mg (TW)</i>	
.CARDIOVASCULAR SYSTEM	132
<i>Terry White Chemists Cefaclor CD (TW)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	234
<i>Terry White Chemists Celecoxib (TW)</i>	
.MUSCULO-SKELETAL SYSTEM	495
<i>Terry White Chemists Cephalexin (TW)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	231, 232, 233
<i>Terry White Chemists Citalopram (TW)</i>	
.NERVOUS SYSTEM.....	564
<i>Terry White Chemists Clarithromycin (TW)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	238
<i>Terry White Chemists Clindamycin (TW)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	240
<i>Terry White Chemists Clomipramine (TW)</i>	
.NERVOUS SYSTEM.....	563
<i>Terry White Chemists Clopidogrel (TW)</i>	
.BLOOD AND BLOOD FORMING ORGANS.....	107
.Repatriation Schedule	1248
<i>Terry White Chemists Clopidogrel/Aspirin 75/100 (TW)</i>	
.BLOOD AND BLOOD FORMING ORGANS.....	108
<i>Terry White Chemists Diclofenac (TW)</i>	
.MUSCULO-SKELETAL SYSTEM	490
.Palliative Care.....	667, 668
<i>Terry White Chemists Diltiazem CD (TW)</i>	
.CARDIOVASCULAR SYSTEM	134
<i>Terry White Chemists Donepezil (TW)</i>	
.NERVOUS SYSTEM.....	576, 577, 578
<i>Terry White Chemists Doxycycline (TW)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	223, 224
<i>Terry White Chemists Duloxetine (TW)</i>	
.NERVOUS SYSTEM.....	570, 571
<i>Terry White Chemists Enalapril (TW)</i>	
.CARDIOVASCULAR SYSTEM	135
<i>Terry White Chemists Escitalopram (TW)</i>	
.NERVOUS SYSTEM.....	565
<i>Terry White Chemists Famciclovir (TW)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	252, 253
<i>Terry White Chemists Famotidine (TW)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	61
<i>Terry White Chemists Fluoxetine (TW)</i>	
.NERVOUS SYSTEM.....	567
<i>Terry White Chemists Frusemide (TW)</i>	
.CARDIOVASCULAR SYSTEM	126, 127
<i>Terry White Chemists Gemfibrozil (TW)</i>	
.CARDIOVASCULAR SYSTEM	169
<i>Terry White Chemists Glipizide (TW)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	84
<i>Terry White Chemists Glipizide MR (TW)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	84

GENERIC/PROPRIETARY INDEX

<i>Terry White Chemists Hydroxychloroquine (TW)</i> .MUSCULO-SKELETAL SYSTEM 495	<i>Terry White Chemists Perindopril/ Indapamide 4/1.25 (TW)</i> .CARDIOVASCULAR SYSTEM 142
<i>Terry White Chemists Indapamide (TW)</i> .CARDIOVASCULAR SYSTEM 126	<i>Terry White Chemists Pioglitazone (TW)</i> .ALIMENTARY TRACT AND METABOLISM 92
<i>Terry White Chemists Indapamide SR (TW)</i> .CARDIOVASCULAR SYSTEM 126	<i>Terry White Chemists Piroxicam (TW)</i> .MUSCULO-SKELETAL SYSTEM 492, 493
<i>Terry White Chemists Irbesartan (TW)</i> .CARDIOVASCULAR SYSTEM 145, 146	<i>Terry White Chemists Pravastatin (TW)</i> .CARDIOVASCULAR SYSTEM 159, 160, 161
<i>Terry White Chemists Irbesartan HCTZ (TW)</i> .CARDIOVASCULAR SYSTEM 149, 150	<i>Terry White Chemists Prazosin (TW)</i> .CARDIOVASCULAR SYSTEM 125
<i>Terry White Chemists Isosorbide Mononitrate (TW)</i> .CARDIOVASCULAR SYSTEM 124	<i>Terry White Chemists Quetiapine (TW)</i> .NERVOUS SYSTEM 552, 553, 554
<i>Terry White Chemists Latanoprost (TW)</i> .SENSORY ORGANS 612, 613	<i>Terry White Chemists Rabeprazole (TW)</i> .ALIMENTARY TRACT AND METABOLISM 66, 67
<i>Terry White Chemists Lercanidipine (TW)</i> .CARDIOVASCULAR SYSTEM 133	<i>Terry White Chemists Raloxifene (TW)</i> .MUSCULO-SKELETAL SYSTEM 508
<i>Terry White Chemists Letrozole (TW)</i> .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS 299	<i>Terry White Chemists Ramipril (TW)</i> .CARDIOVASCULAR SYSTEM 138, 139, 140
<i>Terry White Chemists Levetiracetam (TW)</i> .NERVOUS SYSTEM 535, 536	<i>Terry White Chemists Ranitidine (TW)</i> .ALIMENTARY TRACT AND METABOLISM 61
<i>Terry White Chemists Lisinopril (TW)</i> .CARDIOVASCULAR SYSTEM 136	<i>Terry White Chemists Risedronate (TW)</i> .MUSCULO-SKELETAL SYSTEM 500
<i>Terry White Chemists Meloxicam (TW)</i> .MUSCULO-SKELETAL SYSTEM 491, 492	<i>Terry White Chemists Rosuvastatin (TW)</i> .CARDIOVASCULAR SYSTEM ... 162, 163, 164, 165, 166
<i>Terry White Chemists Meloxicam 15 mg (TW)</i> .MUSCULO-SKELETAL SYSTEM 491	<i>Terry White Chemists Roxithromycin (TW)</i> .ANTIINFECTIVES FOR SYSTEMIC USE 239, 240
<i>Terry White Chemists Meloxicam 7.5 mg (TW)</i> .MUSCULO-SKELETAL SYSTEM 492	<i>Terry White Chemists Sertraline (TW)</i> .NERVOUS SYSTEM 568, 569
<i>Terry White Chemists Metformin (TW)</i> .ALIMENTARY TRACT AND METABOLISM 83, 84	<i>Terry White Chemists Sildenafil (TW)</i> .Repatriation Schedule 1256
<i>Terry White Chemists Metformin 1000 (TW)</i> .ALIMENTARY TRACT AND METABOLISM 83	<i>Terry White Chemists Simvastatin (TW)</i> .CARDIOVASCULAR SYSTEM 166, 167, 168
<i>Terry White Chemists Metformin XR 500 (TW)</i> .ALIMENTARY TRACT AND METABOLISM 84	<i>Terry White Chemists Sotalol (TW)</i> .CARDIOVASCULAR SYSTEM 122
<i>Terry White Chemists Metoprolol (TW)</i> .CARDIOVASCULAR SYSTEM 130	<i>Terry White Chemists Sumatriptan (TW)</i> .NERVOUS SYSTEM 526, 527
<i>Terry White Chemists Mirtazapine (TW)</i> .NERVOUS SYSTEM 572	<i>Terry White Chemists Telmisartan (TW)</i> .CARDIOVASCULAR SYSTEM 146, 147
<i>Terry White Chemists Moclobemide (TW)</i> .NERVOUS SYSTEM 569, 570	<i>Terry White Chemists Telmisartan HCTZ 40/12.5 (TW)</i> .CARDIOVASCULAR SYSTEM 150
<i>Terry White Chemists Montelukast (TW)</i> .RESPIRATORY SYSTEM 603, 604	<i>Terry White Chemists Telmisartan HCTZ 80/12.5 (TW)</i> .CARDIOVASCULAR SYSTEM 151
<i>Terry White Chemists Olanzapine (TW)</i> .NERVOUS SYSTEM 547, 549, 550, 552	<i>Terry White Chemists Telmisartan HCTZ 80/25 (TW)</i> .CARDIOVASCULAR SYSTEM 151
<i>Terry White Chemists Olanzapine ODT (TW)</i> .NERVOUS SYSTEM 546, 548, 549	<i>Terry White Chemists Tramadol (TW)</i> .NERVOUS SYSTEM 522, 523
<i>Terry White Chemists Omeprazole (TW)</i> .ALIMENTARY TRACT AND METABOLISM 64	<i>Terry White Chemists Tramadol SR (TW)</i> .NERVOUS SYSTEM 521, 522
<i>Terry White Chemists Pantoprazole (TW)</i> .ALIMENTARY TRACT AND METABOLISM 65, 66	<i>Terry White Chemists Valaciclovir (TW)</i> .ANTIINFECTIVES FOR SYSTEMIC USE 253, 254
<i>Terry White Chemists Paroxetine (TW)</i> .NERVOUS SYSTEM 568	<i>Terry White Chemists Venlafaxine XR (TW)</i> .NERVOUS SYSTEM 572, 573
<i>Terry White Chemists Perindopril (TW)</i> .CARDIOVASCULAR SYSTEM 137, 138	<i>Tertroxin (QA)</i>

GENERIC/PROPRIETARY INDEX

.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS.....	219	<i>Tielle MTL101E (KI)</i> .Repatriation Schedule	1281
<i>Testogel (HB)</i> .GENITO URINARY SYSTEM AND SEX HORMONES .	204	<i>Tilade CFC-Free (SW)</i> .RESPIRATORY SYSTEM.....	602
TESTOSTERONE .GENITO URINARY SYSTEM AND SEX HORMONES .	202	TILUDRONATE .MUSCULO-SKELETAL SYSTEM	500
TESTOSTERONE ENANTHATE .GENITO URINARY SYSTEM AND SEX HORMONES .	204	<i>Timentin (AS)</i> .ANTIINFECTIVES FOR SYSTEMIC USE.....	230, 231
TESTOSTERONE UNDECANOATE .GENITO URINARY SYSTEM AND SEX HORMONES .	205	TIMOLOL .SENSORY ORGANS.....	611
TETRABENAZINE .NERVOUS SYSTEM.....	590	TIMOLOL + TRAVOPROST .SENSORY ORGANS.....	613, 614
TETRACOSACTRIN .SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS.....	214	<i>Timoptol (FR)</i> .SENSORY ORGANS.....	611
<i>TevaGrastim (AS)</i> .Section 100	760, 761, 1018	<i>Timoptol XE (MK)</i> .SENSORY ORGANS.....	611
<i>Teveten (GO)</i> .CARDIOVASCULAR SYSTEM	144, 145	<i>Tinaderm (BN)</i> .Repatriation Schedule	1250
<i>Teveten Plus 600/12.5 (GO)</i> .CARDIOVASCULAR SYSTEM	148	<i>Tinasil (AF)</i> .DERMATOLOGICALS	193
THALIDOMIDE .Section 100	917, 1175	.Repatriation Schedule	1251
<i>Thalomid (CJ)</i> .Section 100	917, 1175	TINIDAZOLE .ANTIINFECTIVES FOR SYSTEMIC USE	245
THEOPHYLLINE .RESPIRATORY SYSTEM	603	TIOTROPIUM .RESPIRATORY SYSTEM.....	602
<i>TheraTears (CX)</i> .SENSORY ORGANS.....	619, 620	TIPRANAVIR .Section 100.....	744, 1000
THIAMINE .ALIMENTARY TRACT AND METABOLISM.....	100	TIROFIBAN .BLOOD AND BLOOD FORMING ORGANS.....	109
.Repatriation Schedule	1246	<i>Tirofiban AC (GN)</i> .BLOOD AND BLOOD FORMING ORGANS.....	110
THIOGUANINE .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	258	<i>Titralac (MM)</i> .Repatriation Schedule	1244
<i>Thioprine (AF)</i> .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	489	<i>Tivicay (VI)</i> .Section 100.....	754, 1012
<i>Thyrogen (GZ)</i> .SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS.....	214	<i>Tobi (NV)</i> .ANTIINFECTIVES FOR SYSTEMIC USE.....	241
THYROTROPIN ALFA .SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS.....	214	<i>TOBI podhaler (NV)</i> .ANTIINFECTIVES FOR SYSTEMIC USE.....	241
THYROXINE .SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS.....	219	<i>Tobra-Day (PL)</i> .ANTIINFECTIVES FOR SYSTEMIC USE.....	242
TIAGABINE .NERVOUS SYSTEM.....	530	TOBRAMYCIN .ANTIINFECTIVES FOR SYSTEMIC USE.....	240, 241, 242
TICAGRELOR .BLOOD AND BLOOD FORMING ORGANS	109	.SENSORY ORGANS.....	605, 606
TICARCILLIN + CLAVULANIC ACID .ANTIINFECTIVES FOR SYSTEMIC USE.....	230, 231	<i>Tobrex (AQ)</i> .SENSORY ORGANS.....	606
<i>Tielle MT2442 (KI)</i> .Repatriation Schedule	1281	TOCILIZUMAB .Section 100.....	869, 878, 886, 893, 1127, 1136, 1145, 1151
		<i>Tofranil 10 (LM)</i> .NERVOUS SYSTEM.....	564
		<i>Tofranil 25 (LM)</i> .NERVOUS SYSTEM.....	564
		<i>Tolerade 10 (PQ)</i> .NERVOUS SYSTEM.....	564

GENERIC/PROPRIETARY INDEX

<i>Toleraide 25 (PQ)</i>		
.NERVOUS SYSTEM.....	564	
<i>TOLNAFTATE</i>		
.Repatriation Schedule.....	1250	
<i>Topamax (JC)</i>		
.NERVOUS SYSTEM.....	537, 538	
<i>Topamax Sprinkle (JC)</i>		
.NERVOUS SYSTEM.....	537	
<i>TOPIRAMATE</i>		
.NERVOUS SYSTEM.....	537	
<i>Topiramate AN (EA)</i>		
.NERVOUS SYSTEM.....	537, 538	
<i>Topiramate GH (GQ)</i>		
.NERVOUS SYSTEM.....	537, 538	
<i>Topiramate Sandoz (SZ)</i>		
.NERVOUS SYSTEM.....	537, 538	
<i>Topra 40 (DO)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	65, 66	
<i>Toprol-XL 190 (AP)</i>		
.CARDIOVASCULAR SYSTEM.....	130	
<i>Toprol-XL 23.75 (AP)</i>		
.CARDIOVASCULAR SYSTEM.....	130	
<i>Toprol-XL 47.5 (AP)</i>		
.CARDIOVASCULAR SYSTEM.....	130	
<i>Toprol-XL 95 (AP)</i>		
.CARDIOVASCULAR SYSTEM.....	130	
<i>TOREMIFENE</i>		
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS.....	294	
<i>Torlemo DT 100 (UA)</i>		
.NERVOUS SYSTEM.....	534	
<i>Torlemo DT 200 (UA)</i>		
.NERVOUS SYSTEM.....	534	
<i>Torlemo DT 25 (UA)</i>		
.NERVOUS SYSTEM.....	534	
<i>Torlemo DT 50 (UA)</i>		
.NERVOUS SYSTEM.....	535	
<i>Torvastat 10 (QA)</i>		
.CARDIOVASCULAR SYSTEM.....	157, 158	
<i>Torvastat 20 (QA)</i>		
.CARDIOVASCULAR SYSTEM.....	157, 158	
<i>Torvastat 40 (QA)</i>		
.CARDIOVASCULAR SYSTEM.....	157, 158	
<i>Torvastat 80 (QA)</i>		
.CARDIOVASCULAR SYSTEM.....	157, 159	
<i>Torzole 20 (VN)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	65	
<i>Torzole 40 (VN)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	65, 66	
<i>Tracleer (AT)</i>		
.Section 100.....	699, 705, 954, 960	
<i>Trajenta (BY)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	94	
<i>Trajentamet (BY)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	87	
<i>TRAMADOL</i>		
.NERVOUS SYSTEM.....	521, 522, 523	
<i>Tramadol ACT (GN)</i>		
.NERVOUS SYSTEM.....	522	
.Prescriber Bag.....	58	
<i>Tramadol Actavis (UA)</i>		
.NERVOUS SYSTEM.....	522, 523	
<i>Tramadol AN (EA)</i>		
.NERVOUS SYSTEM.....	522, 523	
<i>Tramadol AN SR (EA)</i>		
.NERVOUS SYSTEM.....	521, 522	
<i>Tramadol Sandoz (SZ)</i>		
.NERVOUS SYSTEM.....	522, 523	
.Prescriber Bag.....	58	
<i>Tramadol Sandoz SR (SZ)</i>		
.NERVOUS SYSTEM.....	521, 522	
<i>Tramadol SCP (CR)</i>		
.NERVOUS SYSTEM.....	522, 523	
<i>Tramadol SR generichealth (GQ)</i>		
.NERVOUS SYSTEM.....	521, 522	
<i>Tramal (CS)</i>		
.NERVOUS SYSTEM.....	521, 522, 523	
<i>Tramal 100 (CS)</i>		
.NERVOUS SYSTEM.....	522	
.Prescriber Bag.....	58	
<i>Tramal SR 100 (CS)</i>		
.NERVOUS SYSTEM.....	521	
<i>Tramal SR 150 (CS)</i>		
.NERVOUS SYSTEM.....	521	
<i>Tramal SR 200 (CS)</i>		
.NERVOUS SYSTEM.....	522	
<i>Tramal SR 50 (CS)</i>		
.NERVOUS SYSTEM.....	522	
<i>Tramedo (AF)</i>		
.NERVOUS SYSTEM.....	522, 523	
<i>Tramedo SR 100 (AF)</i>		
.NERVOUS SYSTEM.....	521	
<i>Tramedo SR 150 (AF)</i>		
.NERVOUS SYSTEM.....	521	
<i>Tramedo SR 200 (AF)</i>		
.NERVOUS SYSTEM.....	522	
<i>Tranalpha (AF)</i>		
.CARDIOVASCULAR SYSTEM.....	140	
<i>Trandate (QA)</i>		
.CARDIOVASCULAR SYSTEM.....	132	
<i>TRANDOLAPRIL</i>		
.CARDIOVASCULAR SYSTEM.....	140	
<i>TRANDOLAPRIL + VERAPAMIL</i>		
.CARDIOVASCULAR SYSTEM.....	143	
<i>Trandolapril-DP (GN)</i>		
.CARDIOVASCULAR SYSTEM.....	140	
<i>TRANEXAMIC ACID</i>		
.BLOOD AND BLOOD FORMING ORGANS.....	118	
<i>Transiderm-Nitro 25 (NV)</i>		
.CARDIOVASCULAR SYSTEM.....	123	

GENERIC/PROPRIETARY INDEX

<i>Transiderm-Nitro 50 (NV)</i>		
.CARDIOVASCULAR SYSTEM	123	
<i>TRANLYCYPROMINE</i>		
.NERVOUS SYSTEM.....	569	
<i>Travatan (AQ)</i>		
.SENSORY ORGANS.....	614	
<i>TRAVOPROST</i>		
.SENSORY ORGANS.....	614	
<i>TRIAMCINOLONE</i>		
.DERMATOLOGICALS.....	195	
.SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX		
HORMONES AND INSULINS.....	218	
<i>TRIAMCINOLONE + NEOMYCIN SULFATE + GRAMICIDIN</i>		
+ NYSTATIN		
.SENSORY ORGANS.....	624	
<i>Triasyn 2.5/2.5 (SW)</i>		
.CARDIOVASCULAR SYSTEM	143	
<i>Triasyn 5.0/5.0 (SW)</i>		
.CARDIOVASCULAR SYSTEM	143	
<i>Tricortone (FM)</i>		
.DERMATOLOGICALS.....	195	
<i>Trifeme 28 (FZ)</i>		
.GENITO URINARY SYSTEM AND SEX HORMONES .	202	
<i>TRIFLUOPERAZINE</i>		
.NERVOUS SYSTEM.....	544	
<i>TRIGLYCERIDES LONG CHAIN</i>		
.VARIOUS.....	632	
<i>TRIGLYCERIDES LONG CHAIN WITH GLUCOSE POLYMER</i>		
.VARIOUS.....	659	
<i>TRIGLYCERIDES MEDIUM CHAIN</i>		
.VARIOUS.....	632	
<i>TRIGLYCERIDES MEDIUM CHAIN AND LONG CHAIN WITH</i>		
GLUCOSE POLYMER		
.VARIOUS.....	659	
<i>TRIGLYCERIDES MEDIUM CHAIN FORMULA</i>		
.VARIOUS.....	648, 659	
<i>Trileptal (NV)</i>		
.NERVOUS SYSTEM.....	530	
<i>TRIMETHOPRIM</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	237	
<i>TRIMETHOPRIM + SULFAMETHOXAZOLE</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	237	
<i>Triphasil 28 (PF)</i>		
.GENITO URINARY SYSTEM AND SEX HORMONES .	202	
<i>Triprim (QA)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	237	
<i>TRIPTORELIN</i>		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	294	
<i>Triquilar ED (BN)</i>		
.GENITO URINARY SYSTEM AND SEX HORMONES .	202	
<i>Tritace (SW)</i>		
.CARDIOVASCULAR SYSTEM	139	
<i>Tritace 1.25 mg (SW)</i>		
.CARDIOVASCULAR SYSTEM	138	
<i>Tritace 10 mg (SW)</i>		
.CARDIOVASCULAR SYSTEM	139	
<i>Tritace 2.5 mg (SW)</i>		
.CARDIOVASCULAR SYSTEM	139	
<i>Tritace 5 mg (SW)</i>		
.CARDIOVASCULAR SYSTEM	140	
<i>Tritace Titration Pack (SW)</i>		
.CARDIOVASCULAR SYSTEM	139	
<i>Triumeq (VI)</i>		
.Section 100.....	752, 1009	
<i>Trizivir (VI)</i>		
.Section 100.....	752, 1009	
<i>TROPISETRON</i>		
.ALIMENTARY TRACT AND METABOLISM.....	71	
<i>Tropisetron-AFT (AE)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	71	
<i>Trovas (RA)</i>		
.CARDIOVASCULAR SYSTEM	157, 158, 159	
<i>TRUEbalance (NX)</i>		
.VARIOUS.....	630, 631	
<i>TRUEresult (NX)</i>		
.VARIOUS.....	630, 631	
<i>TRUEtrack (NX)</i>		
.VARIOUS.....	630, 631	
<i>Trusamide (QA)</i>		
.SENSORY ORGANS.....	610	
<i>Trusopt (MK)</i>		
.SENSORY ORGANS.....	610	
<i>Truvada (GI)</i>		
.Section 100.....	753, 1011	
<i>Tryzan Caps 1.25 (AF)</i>		
.CARDIOVASCULAR SYSTEM	138	
<i>Tryzan Caps 10 (AF)</i>		
.CARDIOVASCULAR SYSTEM	139	
<i>Tryzan Caps 2.5 (AF)</i>		
.CARDIOVASCULAR SYSTEM	139	
<i>Tryzan Caps 5 (AF)</i>		
.CARDIOVASCULAR SYSTEM	140	
<i>Tryzan Tabs 1.25 (AF)</i>		
.CARDIOVASCULAR SYSTEM	138	
<i>Tryzan Tabs 10 (AF)</i>		
.CARDIOVASCULAR SYSTEM	139	
<i>Tryzan Tabs 2.5 (AF)</i>		
.CARDIOVASCULAR SYSTEM	139	
<i>Tryzan Tabs 5 (AF)</i>		
.CARDIOVASCULAR SYSTEM	140	
<i>Tubegauz 0501633 (SS)</i>		
.Repatriation Schedule	1275	
<i>Tubifast 2434 (MH)</i>		
.Repatriation Schedule	1275	
<i>Tubifast 2436 (MH)</i>		
.Repatriation Schedule	1275	
<i>Tubifast 2438 (MH)</i>		
.Repatriation Schedule	1275	
<i>Tubigrip 1479 (MH)</i>		

GENERIC/PROPRIETARY INDEX

.Repatriation Schedule	1276
<i>Tubigrip 1480 (MH)</i>	
.Repatriation Schedule	1275
<i>Tubigrip 1481 (MH)</i>	
.Repatriation Schedule	1275
<i>Tubigrip 1482 (MH)</i>	
.Repatriation Schedule	1275
<i>Tubigrip 1483 (MH)</i>	
.Repatriation Schedule	1275
<i>Tubigrip 1484 (MH)</i>	
.Repatriation Schedule	1275
<i>Tubigrip 1486 (MH)</i>	
.Repatriation Schedule	1275
<i>Tubigrip B 1520 (MH)</i>	
.Repatriation Schedule	1275
<i>Tubigrip C 1545 (MH)</i>	
.Repatriation Schedule	1275
<i>Tubigrip D 1546 (MH)</i>	
.Repatriation Schedule	1275
<i>Tubigrip E 1547 (MH)</i>	
.Repatriation Schedule	1275
<i>Tubigrip F 1548 (MH)</i>	
.Repatriation Schedule	1275
<i>Twynsta (BY)</i>	
.CARDIOVASCULAR SYSTEM	152
<i>Tykerb (GK)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	280
<i>TYR Anamix infant (SB)</i>	
.VARIOUS	654
<i>TYR Anamix Junior (SB)</i>	
.VARIOUS	654
<i>TYR Anamix junior LQ (SB)</i>	
.VARIOUS	651
<i>TYR cooler 10 (VF)</i>	
.VARIOUS	654
<i>TYR cooler 15 (VF)</i>	
.VARIOUS	654
<i>TYR cooler 20 (VF)</i>	
.VARIOUS	654
<i>TYR express 15 (VF)</i>	
.VARIOUS	654
<i>TYR gel (VF)</i>	
.VARIOUS	654
<i>TYR Lophlex LQ 20 (SB)</i>	
.VARIOUS	654
<i>Tyrosine 1000 (VF)</i>	
.VARIOUS	659
TYROSINE WITH CARBOHYDRATE	
.VARIOUS	659
<i>Tysabri (BD)</i>	
.Section 100	803, 1061

U

<i>Ulcaid (RA)</i>	
.ALIMENTARY TRACT AND METABOLISM	61
<i>Ulcye (AF)</i>	
.ALIMENTARY TRACT AND METABOLISM	67
<i>ultibro breezhaler 110/50 (NV)</i>	
.RESPIRATORY SYSTEM	599
UMECLIDINIUM	
.RESPIRATORY SYSTEM	602
UMECLIDINIUM + VILANTEROL	
.RESPIRATORY SYSTEM	599
<i>Uracol (GN)</i>	
.Repatriation Schedule	1257
<i>Ural Sachets (QA)</i>	
.Repatriation Schedule	1257
UREA	
.Repatriation Schedule	1251
<i>Urederm (IA)</i>	
.Repatriation Schedule	1251
<i>Uremide (AF)</i>	
.CARDIOVASCULAR SYSTEM	126
<i>Urex (FM)</i>	
.CARDIOVASCULAR SYSTEM	126
<i>Urex-Forte (FM)</i>	
.CARDIOVASCULAR SYSTEM	127
<i>Urex-M (FM)</i>	
.CARDIOVASCULAR SYSTEM	127
<i>Uro-Carb (YN)</i>	
.NERVOUS SYSTEM	584
<i>Uromitexan (BX)</i>	
.VARIOUS	628
URSODEOXYCHOLIC ACID	
.ALIMENTARY TRACT AND METABOLISM	72
<i>Ursofalk (OA)</i>	
.ALIMENTARY TRACT AND METABOLISM	72
<i>Ursosan (BZ)</i>	
.ALIMENTARY TRACT AND METABOLISM	73
USTEKINUMAB	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS	480, 485

V

<i>Vaclovir (AF)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE	253, 254
<i>Vagifem Low (NO)</i>	
.GENITO URINARY SYSTEM AND SEX HORMONES .	207
VALACICLOVIR	
.ANTIINFECTIVES FOR SYSTEMIC USE	253, 254
.Section 100	737, 993
<i>Valaciclovir Actavis (VN)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE	253, 254
<i>Valaciclovir AN (EA)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE	253, 254, 255

GENERIC/PROPRIETARY INDEX

<i>Valaciclovir GA (GN)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	253, 254, 255	
<i>Valaciclovir generichealth (GQ)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	254, 255	
<i>Valaciclovir RBX (RA)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	254, 255	
.Section 100	737, 993	
<i>Valaciclovir Sandoz (SZ)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	253, 254, 255	
<i>Valaciclovir SZ (HX)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	254	
<i>Valacor 500 (CR)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	254, 255	
<i>Valcyte (RO)</i>		
.Section 100	738, 994	
VALGANCICLOVIR		
.Section 100	737, 994	
<i>Valine 1000 (VF)</i>		
.VARIOUS.....	659	
<i>Valine 50 (VF)</i>		
.VARIOUS.....	659	
VALINE WITH CARBOHYDRATE		
.VARIOUS.....	659	
<i>Valium (RO)</i>		
.NERVOUS SYSTEM.....	560, 561	
.Palliative Care	674, 675	
<i>Valnir (QA)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	253, 254, 255	
<i>Valpam 2 (QA)</i>		
.NERVOUS SYSTEM.....	560, 561	
.Palliative Care	674, 675	
<i>Valpam 5 (QA)</i>		
.NERVOUS SYSTEM.....	560, 561	
.Palliative Care	674, 675	
<i>Valprease 200 (QA)</i>		
.NERVOUS SYSTEM.....	530	
<i>Valprease 500 (QA)</i>		
.NERVOUS SYSTEM.....	531	
<i>Valpro 200 (AF)</i>		
.NERVOUS SYSTEM.....	530	
<i>Valpro 500 (AF)</i>		
.NERVOUS SYSTEM.....	531	
VALPROATE		
.NERVOUS SYSTEM.....	530	
<i>Valproate Winthrop EC 200 (WA)</i>		
.NERVOUS SYSTEM.....	530	
<i>Valproate Winthrop EC 500 (WA)</i>		
.NERVOUS SYSTEM.....	531	
VALSARTAN		
.CARDIOVASCULAR SYSTEM	147	
VALSARTAN + HYDROCHLOROTHIAZIDE		
.CARDIOVASCULAR SYSTEM	151	
<i>Valsartan/Amlodipine Sandoz 80/5 (NM)</i>		
.CARDIOVASCULAR SYSTEM	152	
<i>Valsartan/Amlodipine/HCT Sandoz 160/5/12.5 (NM)</i>		
.CARDIOVASCULAR SYSTEM	153	
<i>Valtrex (AS)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	253, 254, 255	
.Section 100.....	737, 994	
<i>Vancocin (AS)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	76	
<i>Vancocin CP (AS)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	243, 244	
VANCOMYCIN		
.ALIMENTARY TRACT AND METABOLISM.....	76	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	243	
<i>Vancomycin Alphapharm (AF)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	243, 244	
<i>Vancomycin Sandoz (SZ)</i>		
.ANTIINFECTIVES FOR SYSTEMIC USE.....	243, 244	
VARDENAFIL		
.Repatriation Schedule	1257	
VARENICLINE		
.NERVOUS SYSTEM.....	586, 587	
<i>Vasafil 100 (QA)</i>		
.Repatriation Schedule	1256	
<i>Vasafil 25 (QA)</i>		
.Repatriation Schedule	1256	
<i>Vasafil 50 (QA)</i>		
.Repatriation Schedule	1257	
<i>Vascalace 1.25 (DO)</i>		
.CARDIOVASCULAR SYSTEM	138	
<i>Vascalace 10 (DO)</i>		
.CARDIOVASCULAR SYSTEM	139	
<i>Vascalace 2.5 (DO)</i>		
.CARDIOVASCULAR SYSTEM	139	
<i>Vascalace 5 (DO)</i>		
.CARDIOVASCULAR SYSTEM	140	
<i>Vascalace Caps 1.25 (DO)</i>		
.CARDIOVASCULAR SYSTEM	138	
<i>Vascalace Caps 10 (DO)</i>		
.CARDIOVASCULAR SYSTEM	139	
<i>Vascalace Caps 2.5 (DO)</i>		
.CARDIOVASCULAR SYSTEM	139	
<i>Vascalace Caps 5 (DO)</i>		
.CARDIOVASCULAR SYSTEM	140	
<i>Vasocardol (AV)</i>		
.CARDIOVASCULAR SYSTEM	134	
<i>Vasocardol CD (AV)</i>		
.CARDIOVASCULAR SYSTEM	134	
<i>Vastin (NM)</i>		
.CARDIOVASCULAR SYSTEM	159	
<i>Vedilol 12.5 (QA)</i>		
.CARDIOVASCULAR SYSTEM	131	
<i>Vedilol 25 (QA)</i>		
.CARDIOVASCULAR SYSTEM	131	
<i>Vedilol 3.125 (QA)</i>		
.CARDIOVASCULAR SYSTEM	131	
<i>Vedilol 6.25 (QA)</i>		
.CARDIOVASCULAR SYSTEM	132	

GENERIC/PROPRIETARY INDEX

<i>Veletri (AT)</i>		
.Section 100	710, 965	
<i>Velphoro (FN)</i>		
.Section 100	934, 1197	
.VARIOUS.....	627	
<i>Venla RBX (RA)</i>		
.NERVOUS SYSTEM.....	573	
<i>VENLAFAXINE</i>		
.NERVOUS SYSTEM.....	572	
<i>Venlafaxine Actavis XR (UA)</i>		
.NERVOUS SYSTEM.....	572, 573	
<i>Venlafaxine AN SR (EA)</i>		
.NERVOUS SYSTEM.....	573	
<i>Venlafaxine generichealth XR (GQ)</i>		
.NERVOUS SYSTEM.....	573	
<i>Venlafaxine Sandoz XR (SZ)</i>		
.NERVOUS SYSTEM.....	573	
<i>Venlafaxine SR SCP 150 (CR)</i>		
.NERVOUS SYSTEM.....	573	
<i>Venlafaxine SR SCP 75 (CR)</i>		
.NERVOUS SYSTEM.....	573	
<i>Venlexor XR (GN)</i>		
.NERVOUS SYSTEM.....	573	
<i>Venofer (AS)</i>		
.BLOOD AND BLOOD FORMING ORGANS	118	
<i>Ventavis (BN)</i>		
.Section 100	716, 971	
<i>Ventolin (GK)</i>		
.RESPIRATORY SYSTEM	603	
<i>Ventolin CFC-free (GK)</i>		
.Prescriber Bag	57	
.RESPIRATORY SYSTEM	594	
<i>Ventolin Nebules (GK)</i>		
.Prescriber Bag	57, 58	
.RESPIRATORY SYSTEM	595	
<i>Ventolin Rotacaps (GK)</i>		
.RESPIRATORY SYSTEM	594	
<i>Vepesid (BQ)</i>		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	259	
<i>Veracaps SR (QA)</i>		
.CARDIOVASCULAR SYSTEM	133, 134	
<i>VERAPAMIL</i>		
.CARDIOVASCULAR SYSTEM	133	
<i>Vermox (IA)</i>		
.Repatriation Schedule	1266	
<i>VERTEPORFIN</i>		
.SENSORY ORGANS.....	617	
<i>VESPULA SPP VENOM</i>		
.VARIOUS.....	626	
<i>Vexazone (AF)</i>		
.ALIMENTARY TRACT AND METABOLISM.....	92	
<i>Vfend (PF)</i>		
.ANTINFECTIVES FOR SYSTEMIC USE.....	248, 249	
<i>Viagra (PF)</i>		
.Repatriation Schedule	1256, 1257	
<i>Victrelis (MK)</i>		
.Section 100.....	739, 996	
<i>Vidaza (CJ)</i>		
.Section 100.....	757, 758, 1014, 1015	
<i>Videx EC (BQ)</i>		
.Section 100.....	745, 1001, 1002	
<i>VIGABATRIN</i>		
.NERVOUS SYSTEM.....	531	
<i>VILDAGLIPTIN</i>		
.ALIMENTARY TRACT AND METABOLISM.....	95	
<i>VILDAGLIPTIN + METFORMIN</i>		
.ALIMENTARY TRACT AND METABOLISM.....	89	
<i>Vimpat (UC)</i>		
.NERVOUS SYSTEM.....	532, 533	
<i>VINORELBINE</i>		
.ANTINEOPLASTIC AND IMMUNOMODULATING		
AGENTS	259	
<i>Viramune (BY)</i>		
.Section 100.....	750, 1007	
<i>Viramune XR (BY)</i>		
.Section 100.....	750, 1007	
<i>Viread (GI)</i>		
.Section 100.....	749, 1006	
<i>Viscopaste 4948 (SN)</i>		
.Repatriation Schedule	1276	
<i>Viscotears (AQ)</i>		
.SENSORY ORGANS.....	619	
<i>Viscotears Gel PF (AQ)</i>		
.SENSORY ORGANS.....	618	
<i>Visken 15 (NV)</i>		
.CARDIOVASCULAR SYSTEM	128	
<i>Vistil (AE)</i>		
.SENSORY ORGANS.....	623	
<i>Vistil Forte (AE)</i>		
.SENSORY ORGANS.....	623	
<i>Visudyne (NV)</i>		
.SENSORY ORGANS.....	618	
<i>Vita-B12 (GH)</i>		
.BLOOD AND BLOOD FORMING ORGANS.....	119	
<i>VITAMINS, MINERALS AND TRACE ELEMENTS WITH</i>		
CARBOHYDRATE		
.VARIOUS.....	659, 660	
<i>VitA-POS (AE)</i>		
.SENSORY ORGANS.....	622	
<i>Volibris (GK)</i>		
.Section 100.....	692, 947	
<i>Volirop 12.5 (DO)</i>		
.CARDIOVASCULAR SYSTEM	131	
<i>Volirop 25 (DO)</i>		
.CARDIOVASCULAR SYSTEM	131	
<i>Volirop 3.125 (DO)</i>		
.CARDIOVASCULAR SYSTEM	131	
<i>Volirop 6.25 (DO)</i>		
.CARDIOVASCULAR SYSTEM	132	

GENERIC/PROPRIETARY INDEX

<i>Voltaren 100 (NV)</i>	
.MUSCULO-SKELETAL SYSTEM	490
.Palliative Care	667
<i>Voltaren 25 (NV)</i>	
.MUSCULO-SKELETAL SYSTEM	490
.Palliative Care	667, 668
<i>Voltaren 50 (NV)</i>	
.MUSCULO-SKELETAL SYSTEM	490
.Palliative Care	667, 668
<i>Voluven 6% (PK)</i>	
.BLOOD AND BLOOD FORMING ORGANS	119
VORICONAZOLE	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	247, 248
<i>Votrient (GK)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	284, 285, 286, 287
<i>Voxam (SZ)</i>	
.NERVOUS SYSTEM.....	567
<i>Vycin IV (GN)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	243, 244
<i>Vytorin (MK)</i>	
.CARDIOVASCULAR SYSTEM	181, 183

W

WARFARIN	
.BLOOD AND BLOOD FORMING ORGANS	104
<i>Wartec Cream (GK)</i>	
.Repatriation Schedule	1252
<i>Waxsol (HM)</i>	
.Repatriation Schedule	1269
<i>Wellvone (AS)</i>	
.ANTIPARASITIC PRODUCTS, INSECTICIDES AND	
REPELLENTS.....	591
WHEY PROTEIN FORMULA SUPPLEMENTED WITH	
AMINO ACIDS, LONG CHAIN POLYUNSATURATED	
FATTY ACIDS, VITAMINS AND MINERALS, LOW IN	
PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE	
.VARIOUS.....	660
WHEY PROTEIN FORMULA SUPPLEMENTED WITH	
AMINO ACIDS, VITAMINS AND MINERALS, AND LOW	
IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE	
.VARIOUS.....	660
WOOL ALCOHOLS	
.Repatriation Schedule	1251

X

<i>Xalacom (PF)</i>	
.SENSORY ORGANS.....	613
<i>Xalamol 50/5 (QA)</i>	
.SENSORY ORGANS.....	613
<i>Xalaprost (QA)</i>	
.SENSORY ORGANS.....	612, 613
<i>Xalatan (PF)</i>	
.SENSORY ORGANS.....	612, 613
<i>Xarelto (BN)</i>	
.BLOOD AND BLOOD FORMING ORGANS.....	114, 115,
116, 117	
<i>Xatral SR (SW)</i>	
.Repatriation Schedule	1257
<i>Xelabine (QA)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	258, 259
<i>Xeloda (RO)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	258, 259
<i>Xenical (RO)</i>	
.Repatriation Schedule	1246
<i>Xeomin (EZ)</i>	
.Section 100.....	1202
<i>Xergic (AF)</i>	
.Repatriation Schedule	1268
<i>Xgeva (AN)</i>	
.MUSCULO-SKELETAL SYSTEM	507
<i>Xifaxan (NE)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	76
XLYS, LOW TRY <i>Maxamaid (SB)</i>	
.VARIOUS.....	652
<i>XMET Maxamaid (SB)</i>	
.VARIOUS.....	652
<i>XMET Maxamum (SB)</i>	
.VARIOUS.....	652
<i>XMTVI Maxamaid (SB)</i>	
.VARIOUS.....	653
<i>XMTVI Maxamum (SB)</i>	
.VARIOUS.....	653
<i>Xolair (NV)</i>	
.Section 100.....	926, 1184, 1189
<i>XP Maxamaid (SB)</i>	
.VARIOUS.....	653
<i>XP Maxamum (SB)</i>	
.VARIOUS.....	653
<i>XPhen, Tyr Maxamaid (SB)</i>	
.VARIOUS.....	654
<i>XPhen, Tyr Maxamum (SB)</i>	
.VARIOUS.....	654
<i>Xtandi (LL)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING	
AGENTS	296
<i>Xydep 100 (GN)</i>	
.NERVOUS SYSTEM.....	568, 569
<i>Xydep 50 (GN)</i>	
.NERVOUS SYSTEM.....	569
<i>Xylocaine Viscous (AP)</i>	
.Repatriation Schedule	1252
<i>Xylocard 500 (AP)</i>	
.CARDIOVASCULAR SYSTEM	121

GENERIC/PROPRIETARY INDEX

Y

<i>Yomax 250 (DO)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	225
<i>Yomax 500 (DO)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	226

Z

<i>Z.S.C. (QA)</i>	
.Repatriation Schedule.....	1254
<i>Zactin (AF)</i>	
.NERVOUS SYSTEM.....	567
<i>Zactin Tablet (AF)</i>	
.NERVOUS SYSTEM.....	567
<i>Zan-Extra 10/10 (GO)</i>	
.CARDIOVASCULAR SYSTEM.....	142
<i>Zan-Extra 10/20 (GO)</i>	
.CARDIOVASCULAR SYSTEM.....	142
<i>Zanidip (GO)</i>	
.CARDIOVASCULAR SYSTEM.....	133
<i>Zantac (AS)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	61
<i>Zantac Syrup (AS)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	61
<i>Zarontin (PF)</i>	
.NERVOUS SYSTEM.....	528
<i>Zarzio (SZ)</i>	
.Section 100.....	761, 1018
<i>Zatamil (EO)</i>	
.DERMATOLOGICALS.....	197
<i>Zavedos (PF)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS.....	259
<i>Zedace (AF)</i>	
.CARDIOVASCULAR SYSTEM.....	134
<i>Zedd 500 (QA)</i>	
.Repatriation Schedule.....	1259
<i>Zeffix (AS)</i>	
.Section 100.....	747, 1003
<i>Zeldox (PF)</i>	
.NERVOUS SYSTEM.....	545
<i>Zelitrex (UA)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	253, 254, 255
.Section 100.....	737, 994
<i>Zentel (AS)</i>	
.ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS.....	592
<i>Zerit (BQ)</i>	
.Section 100.....	747, 1004
<i>Zestril (AP)</i>	
.CARDIOVASCULAR SYSTEM.....	136
<i>Zetlam (AF)</i>	
.Section 100.....	747, 1003
<i>Ziagen (VI)</i>	

.Section 100.....	744, 1001
<i>ZIDOVUDINE</i>	
.Section 100.....	749, 1006
<i>Zilarex (SZ)</i>	
.Repatriation Schedule.....	1268
<i>Zilfojim 4 (DO)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	70
<i>Zilfojim 8 (DO)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	70
<i>Zilfojim ODT 4 (DO)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	69
<i>Zilfojim ODT 8 (DO)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	69
<i>Zimstat (AF)</i>	
.CARDIOVASCULAR SYSTEM.....	166, 167, 168
<i>ZINC OXIDE + MAIZE STARCH + CHLORPHENESIN + TALC- PURIFIED</i>	
.Repatriation Schedule.....	1254
<i>ZINC OXIDE + PERU BALSAM + BENZYL BENZOATE</i>	
.Repatriation Schedule.....	1249
<i>Zinnat (AS)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	235
<i>Zinopril 10 (AL)</i>	
.CARDIOVASCULAR SYSTEM.....	136
<i>Zinopril 20 (AL)</i>	
.CARDIOVASCULAR SYSTEM.....	136
<i>Zinopril 5 (AL)</i>	
.CARDIOVASCULAR SYSTEM.....	136
<i>ZIPRASIDONE</i>	
.NERVOUS SYSTEM.....	545
<i>ZipZoc 66000747 (SN)</i>	
.Repatriation Schedule.....	1276
<i>Zircol (AF)</i>	
.CARDIOVASCULAR SYSTEM.....	133
<i>Zithromax (PF)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	238
.Repatriation Schedule.....	1259
.Section 100.....	737, 993
.SENSORY ORGANS.....	605
<i>Zitrocin (GN)</i>	
.ANTIINFECTIVES FOR SYSTEMIC USE.....	238
.Repatriation Schedule.....	1259
.SENSORY ORGANS.....	605
<i>Zocor (MK)</i>	
.CARDIOVASCULAR SYSTEM.....	166, 167, 168
<i>Zofran (AS)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	70
<i>Zofran syrup 50 mL (AS)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	70
<i>Zofran Zydis (AS)</i>	
.ALIMENTARY TRACT AND METABOLISM.....	69
<i>ZolaCos CP 10.8/50(28) (AP)</i>	
.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS.....	293
<i>ZolaCos CP 10.8/50(84) (AP)</i>	

GENERIC/PROPRIETARY INDEX

.ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS 293	<i>Zovirax</i> (GK) .SENSORY ORGANS..... 606
<i>ZolaCos CP 3.6/50</i> (AP) .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS 293	<i>Zovirax 200 mg</i> (GK) .ANTIINFECTIVES FOR SYSTEMIC USE 250
<i>Zoladex 10.8 Implant</i> (AP) .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS 292	<i>Zovirax 800 mg</i> (GK) .ANTIINFECTIVES FOR SYSTEMIC USE 251
<i>Zoladex Implant</i> (AP) .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS 292	ZUCLOPENTHIXOL DECANOATE .NERVOUS SYSTEM..... 545
ZOLEDRONIC ACID .MUSCULO-SKELETAL SYSTEM 501, 502	<i>Zumenon</i> (GO) .GENITO URINARY SYSTEM AND SEX HORMONES . 207
.Section 100 919, 1177	<i>Zyban</i> (AS) .NERVOUS SYSTEM..... 584
ZOLMITRIPTAN .NERVOUS SYSTEM..... 527	<i>Zydol</i> (QA) .NERVOUS SYSTEM..... 522, 523
<i>Zoloft</i> (PF) .NERVOUS SYSTEM..... 568, 569	<i>Zydol SR 100</i> (QA) .NERVOUS SYSTEM..... 521
<i>Zoltrip</i> (QA) .NERVOUS SYSTEM..... 527	<i>Zydol SR 150</i> (QA) .NERVOUS SYSTEM..... 521
<i>Zomacton</i> (FP) .Section 100 1203	<i>Zydol SR 200</i> (QA) .NERVOUS SYSTEM..... 522
<i>Zometa</i> (NV) .Section 100 919, 1177	<i>Zyloprim</i> (QA) .MUSCULO-SKELETAL SYSTEM 497
<i>Zomig</i> (AP) .NERVOUS SYSTEM..... 527	<i>Zypine</i> (AF) .NERVOUS SYSTEM..... 547, 549, 551, 552
<i>Zonegran</i> (SA) .NERVOUS SYSTEM..... 538	<i>Zypine ODT</i> (AF) .NERVOUS SYSTEM..... 547, 548, 549, 551
ZONISAMIDE .NERVOUS SYSTEM..... 538	<i>Zyprexa</i> (LY) .NERVOUS SYSTEM..... 547, 549, 551, 552
ZOPICLONE .Repatriation Schedule 1264	<i>Zyprexa Relprevv</i> (LY) .NERVOUS SYSTEM..... 550
<i>Zopral</i> (AF) .ALIMENTARY TRACT AND METABOLISM..... 62, 63	<i>Zyprexa Zydís</i> (LY) .NERVOUS SYSTEM..... 548, 549, 551
<i>Zopral ODT</i> (AF) .ALIMENTARY TRACT AND METABOLISM..... 62, 63	<i>Zyrtec</i> (JT) .Repatriation Schedule 1268
<i>Zoton FasTabs</i> (PF) .ALIMENTARY TRACT AND METABOLISM..... 62, 63	<i>Zytiga</i> (JC) .ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS 299

THERAPEUTIC GROUP PREMIUM POLICY

PHARMACEUTICAL BENEFIT ITEMS WHICH HAVE A THERAPEUTIC GROUP PREMIUM WITH EFFECT FROM 1 May 2015

The Schedule of Pharmaceutical Benefits shows differences in price in some therapeutic groups where alternative drugs may have a therapeutic group premium.

The Therapeutic Group Premium Policy applies within narrowly defined therapeutic sub-groups where the drugs concerned are of similar safety and health outcomes.

The Australian Government, through the PBS, subsidises up to the price of the lowest priced drug in the group. This means that consumers may have to pay for more expensive drugs (those with a therapeutic group premium). This extra amount does not count towards their PBS safety net threshold.

Therapeutic group premiums apply where a prescriber has prescribed a drug within a therapeutic group that attracts a therapeutic group premium and has not sought an exemption from Department of Human Services on clinical grounds.

The exemption provisions are:

- adverse effects occurring with all of the base-priced drugs; or
- drug interactions occurring with all of the base-priced drugs; or
- drug interactions expected to occur with all of the base-priced drugs; or
- transfer to a base-priced drug would cause patient confusion resulting in problems with compliance.

The premiums are not a Government charge but reflect the fact that the supplier(s) of the drug charge a price higher than the Government is willing to subsidise.

Under the Therapeutic Group Premium Policy drug substitution by pharmacists is not permitted.

For ease of prescribing and dispensing, and in the interests of your patients, the following list shows those PBS drugs that attract a therapeutic group premium.

Premium Priced Brand	Form and Strength	Therapeutic Group Premium \$
ANGIOTENSIN II ANTAGONISTS		
Teveten	eprosartan 400 mg tablet, 28	3.50
Teveten	eprosartan 600 mg tablet, 28	3.50
Olmetec	olmesartan medoxomil 20 mg tablet, 30	2.51
Olmetec	olmesartan medoxomil 40 mg tablet, 30	2.51

The base-priced drugs in this therapeutic group are candesartan cilexetil, irbesartan, losartan and valsartan.

BRAND PREMIUM POLICY

BRANDS OF PHARMACEUTICAL BENEFIT ITEMS WHICH HAVE A BRAND PREMIUM AND THAT MAY BE SUBSTITUTED WITH EFFECT FROM 1 May 2015

The Schedule of Pharmaceutical Benefits shows differences in price between some alternative brands of the same drug product.

Manufacturers can develop generic equivalents and apply to have them listed on the PBS. In doing this, manufacturers need to ensure that they comply with the relevant legislation applicable to patents. These brands are clinically equivalent and must undergo the same strict quality controls. Although these brands are designed to act on the body in exactly the same way, they are usually cheaper than the originator brands.

The Australian Government, through the PBS, subsidises up to the price of the lowest priced brand (except in those instances where the lowest priced brand has, as part of its price, a therapeutic group premium). This means that consumers may have to pay extra for more expensive brands (those with a brand premium). This extra amount does not count towards their PBS safety net threshold.

Brand substitution by pharmacists without reference to the prescriber is permitted for PBS prescriptions where:

- the patient agrees to the substitution;
- the brands are identified in the Schedule of Pharmaceutical Benefits as being interchangeable;
- the prescriber has not indicated on the prescription form that substitution is not to occur; and
- substitution is permitted under the relevant State or Territory legislation.

Prescription forms supplied by Department of Human Services contain a box to be ticked where brand substitution is not to take place.

Prescribers not using these prescription forms should endorse the prescription if brand substitution is not permitted. Where a stamp is used for this purpose, the prescriber will be required to initial the stamped statement.

For ease of prescribing and dispensing, and in the interests of your patients, the following list shows those PBS drugs that attract a brand premium and that can be substituted where permitted. They are listed alphabetically, by brand name, with the brand premium and benchmark brand(s) cited in the last column.

Brand Premium

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium \$	Benchmark Priced Brands
Abbocillin-V	phenoxymethylpenicillin 150 mg/5 mL oral liquid, 100 mL	2	1.90	Cilicaine V
Accupril	quinapril 10 mg tablet, 30	30	1.30	Acquin Aspen 10; APO-Quinapril; Aquinafil; Qpril 10
	quinapril 20 mg tablet, 30	30	1.30	Acquin Aspen 20; APO-Quinapril; Aquinafil; Qpril 20; Quinapril-GA; Quinapril generichealth
Actilax	quinapril 5 mg tablet, 30	30	1.30	Acquin Aspen 5; APO-Quinapril; Aquinafil; Qpril 5
	LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1	1	0.89	Dulose; Genlac
	LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1	3	2.67	Dulose; Genlac
Adalat 10	nifedipine 10 mg tablet, 60	60	1.84	Adefin 10
Adalat 20	nifedipine 20 mg tablet, 60	60	2.57	Adefin 20; GenRx Nifedipine
Adalat Oros 30	nifedipine 30 mg tablet: modified release, 30 tablets	30	2.82	Addos XR 30; Adefin XL 30; APO-Nifedipine XR
Adalat Oros 60	nifedipine 60 mg tablet: modified release, 30 tablets	30	2.99	Addos XR 60; Adefin XL 60; APO-Nifedipine XR
Aldactone	spironolactone 100 mg tablet, 100	100	3.16	Spiractin 100
	spironolactone 25 mg tablet, 100	100	2.59	Spiractin 25
Aldomet	methyl dopa 250 mg tablet, 100	100	3.54	Hydopa
Alphagan	brimonidine tartrate 0.2% eye drops, 5 mL	1	1.63	Enidin
Amaryl	glimepiride 1 mg tablet, 30	30	2.89	APO-Glimepiride; Aylide 1; Diapride 1; Dimirel; Glimepiride AN; Glimepiride GA 1; Glimepiride Sandoz
	glimepiride 2 mg tablet, 30	30	2.82	APO-Glimepiride; Aylide 2; Diapride 2; Dimirel; Glimepiride AN; Glimepiride GA 2; Glimepiride Sandoz
	glimepiride 3 mg tablet, 30	30	2.84	APO-Glimepiride; Aylide 3; Diapride 3; Dimirel; Glimepiride AN; Glimepiride GA 3; Glimepiride Sandoz
	glimepiride 4 mg tablet, 30	30	2.84	APO-Glimepiride; Aylide 4; Diapride 4; Dimirel; Glimepiride AN; Glimepiride GA 4; Glimepiride Sandoz
Amoxil	amoxycillin 125 mg/5 mL oral liquid: powder for, 100 mL	1	2.89	Alphamox 125; Amoxycillin Sandoz; APO-Amoxycillin; Bgramin; Chem mart Amoxycillin; GenRx Amoxycillin; Ranmoxy; Terry White Chemists Amoxycillin
	amoxycillin 250 mg capsule, 20	20	2.89	Alphamox 250; Amoxycillin AN; Amoxycillin-GA; Amoxycillin Ranbaxy; Amoxycillin Sandoz; APO-Amoxycillin; Chem mart Amoxycillin; Cilamox; Terry White Chemists Amoxycillin; Yomax 250
	amoxycillin 500 mg capsule, 20	20	3.06	Alphamox 500; Amoxycillin AN; Amoxycillin-GA; Amoxycillin generichealth 500; Amoxycillin Ranbaxy; Amoxycillin Sandoz; APO-Amoxycillin; Chem mart Amoxycillin; Cilamox; Terry White Chemists Amoxycillin; Yomax 500
Amoxil Forte	amoxycillin 250 mg/5 mL oral liquid: powder for, 100 mL	1	2.97	Alphamox 250; Amoxycillin Sandoz; APO-Amoxycillin; Bgramin; Chem mart Amoxycillin; Cilamox; GenRx Amoxycillin; Ranmoxy; Terry White Chemists Amoxycillin
Anafranil 25	clomipramine hydrochloride 25 mg tablet, 50	50	2.74	Chem mart Clomipramine; GenRx Clomipramine; Placil; Terry White Chemists Clomipramine
Anaprox 550	naproxen sodium 550 mg tablet, 50	50	2.17	Crysanal
Androcur	cyproterone acetate 50 mg tablet, 20	20	2.05	Cyprocur 50; Cyprone; Cyprostat; Cyproterone AN; Cyproterone Sandoz; GenRx Cyproterone Acetate; Procur
	cyproterone acetate 50 mg tablet, 50	100	1.88	Cyprocur 50; Cyprone; Cyprostat; Cyproterone AN; Cyproterone Sandoz; Cyrotone; GenRx Cyproterone Acetate; Procur
Androcur-100	cyproterone acetate 100 mg tablet, 50	50	0.80	Cyprocur 100; Cyprostat-100; Cyproterone AN; Cyproterone Sandoz; GenRx Cyproterone Acetate; Procur 100
Anginine Stabilised	glyceryl trinitrate 600 microgram tablet: sublingual, 100 tablets	1	2.94	Lycinate
Aristocort 0.02%	triamcinolone acetonide 0.02% (200 microgram/g) cream, 100 g	2	3.78	Tricortone
	triamcinolone acetonide 0.02% (200 microgram/g) ointment, 100 g	2	3.78	Tricortone
Aropax	paroxetine 20 mg tablet, 30	30	2.52	Chem mart Paroxetine; Extine 20; GenRx Paroxetine; Paroxetine Actavis; Paroxetine AN; Paroxetine-GA; Paroxetine Sandoz; Paxtine; Roxet 20; Terry White Chemists Paroxetine
Astrix	aspirin 100 mg tablet, 112	112	2.32	Mayne Pharma Aspirin; Spren 100
Atacand	candesartan cilexetil 16 mg tablet, 30	30	1.59	Adesan; APO-Candesartan; Auro-Candesartan 16; Candesartan AN; Candesartan Aspen 16; Candesartan-GA; Candesartan GH; Candesartan RBX; Candesartan Sandoz; Chem mart Candesartan; Pharmacor Candesartan 16; Terry White Chemists Candesartan
	candesartan cilexetil 32 mg tablet, 30	30	1.57	Adesan; APO-Candesartan; Auro-Candesartan 32; Candesartan AN; Candesartan Aspen 32; Candesartan-GA; Candesartan GH; Candesartan RBX; Candesartan Sandoz; Chem mart Candesartan; Pharmacor Candesartan 32; Terry White Chemists Candesartan
	candesartan cilexetil 4 mg tablet, 30	30	1.59	Adesan; APO-Candesartan; Auro-Candesartan 4; Candesartan AN; Candesartan Aspen 4; Candesartan-GA; Candesartan GH; Candesartan RBX; Candesartan Sandoz; Chem mart

Brand Premium

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium \$	Benchmark Priced Brands
	candesartan cilexetil 8 mg tablet, 30	30	1.58	Candesartan; Pharmacor Candesartan 4; Terry White Chemists Candesartan
Atacand Plus 16/12.5	candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30	30	2.00	Adesan; APO-Candesartan; Auro-Candesartan 8; Candesartan AN; Candesartan Aspen 8; Candesartan-GA; Candesartan GH; Candesartan RBX; Candesartan Sandoz; Chem mart Candesartan; Pharmacor Candesartan 8; Terry White Chemists Candesartan
Atacand Plus 32/12.5	candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30	30	2.02	Adesan HCT 16/12.5; APO-Candesartan HCTZ 16/12.5; Candesartan/HCT Sandoz; Candesartan Combi Aspen 16/12.5; Candesartan HCT GH 16/12.5; Candesartan HCTZ AN 16/12.5; Candesartan HCTZ-GA 16/12.5; Candesartan HCTZ RBX 16/12.5; Chem mart Candesartan HCTZ 16/12.5; Pharmacor Candesartan HCT 16/12.5; Terry White Chemists Candesartan HCTZ 16/12.5
Atacand Plus 32/25	candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30	30	2.00	Adesan HCT 32/12.5; APO-Candesartan HCTZ 32/12.5; Candesartan/HCT Sandoz; Candesartan Combi Aspen 32/12.5; Candesartan HCT GH 32/12.5; Candesartan HCTZ AN 32/12.5; Candesartan HCTZ-GA 32/12.5; Candesartan HCTZ RBX 32/12.5; Chem mart Candesartan HCTZ 32/12.5; Pharmacor Candesartan HCT 32/12.5; Terry White Chemists Candesartan HCTZ 32/12.5
Atrovent	ipratropium bromide 250 microgram/mL inhalation: solution, 30 x 1 mL ampoules	2	0.52	Aeron 250; APO-Ipratropium; Ipratrin
Atrovent Adult	ipratropium bromide 500 microgram/mL inhalation: solution, 30 x 1 mL ampoules	2	0.48	Aeron 500; APO-Ipratropium; Ipratrin Adult
Augmentin	amoxycillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL oral liquid: powder for, 75 mL	1	2.89	APO-Amoxycillin and Clavulanic Acid 125/31.25; Clamoxyl; Curam; GA-Amclav 125/31.25
Augmentin Duo	amoxycillin 500 mg + clavulanic acid 125 mg tablet, 10	10	4.00	Amoxyclav AN 500/125; APO-Amoxycillin/ Clavulanic Acid 500/125; Clamoxyl Duo; Curam Duo 500/125; GA-Amclav 500/125; Moxiclav Duo 500/125; Pharmacor AmoxyClav 500/125
Augmentin Duo 400	amoxycillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL oral liquid: powder for, 60 mL	1	4.06	APO-Amoxycillin and Clavulanic Acid 400/57; Clamoxyl Duo 400; Curam Duo; GA-Amclav Forte 400/57
Augmentin Duo forte	amoxycillin 875 mg + clavulanic acid 125 mg tablet, 10	10	5.12	Amoxyclav AN 875/125; AmoxyClav GH 875/125; AmoxyClav RBX 875/125; APO-Amoxycillin and Clavulanic Acid; Chem mart Amoxycillin and Clavulanic Acid; Clamoxyl Duo forte; Clavam 875 mg/125 mg; Curam Duo Forte 875/125; GA-Amclav Forte 875/125; Moxiclav Duo Forte 875/125; Pharmacor AmoxyClav 875/125; Terry White Chemists Amoxycillin and Clavulanic Acid
Aurorix	moclobemide 150 mg tablet, 60	60	0.37	Amira 150; Chem mart Moclobemide; Clobemix; GenRx Moclobemide; Moclobemide AN; Moclobemide Sandoz; Mohexal; Terry White Chemists Moclobemide
Aurorix 300 mg	moclobemide 300 mg tablet, 60	60	0.74	Amira 300; Chem mart Moclobemide; Clobemix; GenRx Moclobemide; Moclobemide AN; Moclobemide Sandoz; Terry White Chemists Moclobemide
Avanza	mirtazapine 30 mg tablet, 30	30	2.99	APO-Mirtazapine; Aurozapine 30; Axit 30; Chem mart Mirtazapine; GenRx Mirtazapine; Mirtazapine AN; Mirtazapine-GA; Mirtazapine GH; Mirtazapine Sandoz; Mirtazon; Terry White Chemists Mirtazapine
	mirtazapine 45 mg tablet, 30	30	2.99	APO-Mirtazapine; Aurozapine 45; Axit 45; Chem mart Mirtazapine; Mirtazapine AN; Mirtazapine-GA; Mirtazapine GH; Mirtazapine Sandoz; Mirtazon; Terry White Chemists Mirtazapine
Avanza SolTab	MIRTAZAPINE Tablet 15 mg (orally disintegrating), 30	30	1.03	Milivin OD 15; Mirtazapine AN ODT; Mirtazapine Sandoz ODT 15; Remeron SolTab
	MIRTAZAPINE Tablet 30 mg (orally disintegrating), 30	30	1.01	Milivin OD 30; Mirtazapine AN ODT; Mirtazapine Sandoz ODT 30; Remeron SolTab
	MIRTAZAPINE Tablet 45 mg (orally disintegrating), 30	30	1.02	Milivin OD 45; Mirtazapine AN ODT; Mirtazapine Sandoz ODT 45; Remeron SolTab
Azopt	brinzolamide 1% eye drops, 5 mL	1	1.18	BrinzoQuin
Betaloc	METOPROLOL TARTRATE Tablet 100 mg, 60	60	3.76	APO-Metoprolol; Chem mart Metoprolol; GenRx Metoprolol; Metoprolol Sandoz; Metrol 100; Minax 100; Terry White Chemists Metoprolol
	METOPROLOL TARTRATE Tablet 50 mg, 100	100	3.76	APO-Metoprolol; Chem mart Metoprolol; GenRx Metoprolol;

Brand Premium

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium \$	Benchmark Priced Brands
				Metoprolol Sandoz; Metrol 50; Minax 50; Terry White Chemists Metoprolol
Betnovate 1/2	betamethasone (as valerate) 0.05% (500 microgram/g) cream, 15 g	1	2.94	Cortival 1/2
Betnovate 1/5	betamethasone (as valerate) 0.02% (200 microgram/g) cream, 100 g	2	6.88	Cortival 1/5
Betoptic	betaxolol 0.5% eye drops, 5 mL	1	2.08	BetoQuin
Bicor	bisoprolol fumarate 10 mg tablet, 28	28	2.60	APO-Bisoprolol; Beprol 10; Bicard 10; Biso 10; Bisoprolol AN; Bisoprolol GH; Bisoprolol Sandoz; Bispro 10; Chem mart Bisoprolol; Terry White Chemists Bisoprolol
	bisoprolol fumarate 2.5 mg tablet, 28	28	2.55	APO-Bisoprolol; Beprol 2.5; Bicard 2.5; Biso 2.5; Bisoprolol AN; Bisoprolol GH; Bisoprolol Sandoz; Bispro 2.5; Chem mart Bisoprolol; Terry White Chemists Bisoprolol
	bisoprolol fumarate 5 mg tablet, 28	28	2.55	APO-Bisoprolol; Beprol 5; Bicard 5; Biso 5; Bisoprolol AN; Bisoprolol GH; Bisoprolol Sandoz; Bispro 5; Chem mart Bisoprolol; Terry White Chemists Bisoprolol
Brevinor	ethinylloestradiol 35 microgram + norethisterone 500 microgram tablet [84] (&) inert substance tablet [28], 112 [4 x 28]	4	10.67	Norimin 28 Day
Brevinor-1	ethinylloestradiol 35 microgram + norethisterone 1 mg tablet [84] (&) inert substance tablet [28], 112 [4 x 28]	4	10.67	Norimin-1 28 Day
Capoten	captopril 25 mg tablet, 90	90	4.47	Captopril Sandoz; GenRx Captopril; Zedace
	captopril 50 mg tablet, 90	90	3.46	Captopril Sandoz; GenRx Captopril; Zedace
Carafate	sucalfate 1 g tablet, 120	120	2.30	Ulcyte
Ceclor	cefaclor 125 mg/5 mL oral liquid: powder for, 100 mL	1	5.86	Aclor 125; APO-Cefaclor; GenRx Cefaclor; Keflor
	cefaclor 250 mg/5 mL oral liquid: powder for, 75 mL	1	6.10	Aclor 250; APO-Cefaclor; GenRx Cefaclor; Keflor
Ceclor CD	cefaclor 375 mg tablet: modified release, 10	10	7.20	APO-Cefaclor CD; Cefaclor-GA; Cefaclor GH; Chem mart Cefaclor CD; GenRx Cefaclor CD; Karlor CD; Keflor CD; Ozcef; Terry White Chemists Cefaclor CD
Celestone-M	betamethasone (as valerate) 0.02% (200 microgram/g) cream, 100 g	2	2.46	Antroquoril
Cellufresh	carmellose sodium 0.5% (2 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses	3	4.77	Optifresh Tears
Celluvisc	carmellose sodium 1% (4 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses	3	4.77	Optifresh Plus
Ciloxan	ciprofloxacin 0.3% eye drops, 5 mL	2	2.06	CiloQuin
Cipramil	citalopram 20 mg tablet, 28	28	5.70	APO-Citalopram; Auro-Citalopram 20; Celapram; Celica; Chem mart Citalopram; Ciazil; Citalopram Actavis; Citalopram AN; Citalopram-GA; Citalopram generichealth; Citalopram Sandoz; Pharmacor Citalo 20; Talam; Terry White Chemists Citalopram
Ciproxin 250	ciprofloxacin 250 mg tablet, 14	14	1.42	C-Flox 250; Ciprofloxacin-DRLA; Ciprofloxacin Sandoz; Ciprol 250; GenRx Ciprofloxacin
Ciproxin 500	ciprofloxacin 500 mg tablet, 14	14	1.40	C-Flox 500; Cifran; Ciprofloxacin 500; Ciprofloxacin AN; Ciprofloxacin-BW; Ciprofloxacin-DRLA; Ciprofloxacin-GA; Ciprofloxacin Sandoz; Ciprol 500; GenRx Ciprofloxacin; Loxip 500
Ciproxin 750	ciprofloxacin 750 mg tablet, 14	14	0.40	C-Flox 750; Cifran; Ciprofloxacin 750; Ciprofloxacin AN; Ciprofloxacin-BW; Ciprofloxacin-DRLA; Ciprofloxacin-GA; Ciprofloxacin Sandoz; Ciprol 750; GenRx Ciprofloxacin; Loxip 750
Colgout	colchicine 500 microgram tablet, 30	30	3.33	Lengout
Coversyl 2.5mg	perindopril arginine 2.5 mg tablet, 30	30	1.65	PREXUM 2.5
Dalacin C	clindamycin 150 mg capsule, 24	24	1.71	APO-Clindamycin; Chem mart Clindamycin; Cleocin; Clindamycin-Link; Terry White Chemists Clindamycin
Daonil	glibenclamide 5 mg tablet, 100	100	1.44	Glimel
Depo-Medrol	methylprednisolone acetate 40 mg/mL injection, 5 x 1 mL vials	5	1.08	Depo-Nisolone
Depo-Provera	medroxyprogesterone acetate 150 mg/mL injection, 1 x 1 mL vial	1	6.19	Depo-Ralovera
Diabex	metformin hydrochloride 500 mg tablet, 100	100	2.52	APO-Metformin 500; Chem mart Metformin; Diaformin; Formet Aspen 500; Glucobete 500; Metformin 500; Metformin AN; Metformin-GA; Metformin generichealth; Metformin Ranbaxy; Metformin Sandoz; Terry White Chemists Metformin
Diabex 1000	metformin hydrochloride 1 g tablet, 90	90	2.51	APO-Metformin 1000; Chem mart Metformin 1000; Diaformin 1000; Formet 1000; Glucobete 1000; Metformin AN; Metformin-GA; Metformin generichealth 1000; Metformin Ranbaxy 1000; Metformin Sandoz; Pharmacor Metformin 1000; Terry White Chemists Metformin 1000
Diabex 850	metformin hydrochloride 850 mg tablet, 60	60	2.52	APO-Metformin 850; Chem mart Metformin; Diaformin 850;

Brand Premium

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium \$	Benchmark Priced Brands
Diabex XR	metformin hydrochloride 500 mg tablet: modified release, 120 tablets	120	2.52	Formet Aspen 850; Glucobete 850; Glucophage; Metformin 850; Metformin AN; Metformin-GA; Metformin generichealth; Metformin Ranbaxy; Metformin Sandoz; Terry White Chemists Metformin
Diabex XR 1000	metformin hydrochloride 1 g tablet: modified release, 60 tablets	60	2.52	APO-Metformin XR 500; Chem mart Metformin XR 500; Diaformin XR; Metex XR; Terry White Chemists Metformin XR 500
Diamicron 60mg MR	glipizide 60 mg tablet: modified release, 60 tablets	60	1.94	APO-Metformin XR 1000; Diaformin XR 1000
Diprosone	betamethasone (as dipropionate) 0.05% cream, 15 g	1	2.45	ARDIX GLICLAZIDE 60mg MR
	betamethasone (as dipropionate) 0.05% ointment, 15 g	1	2.45	Eleuphrat
Doryx	doxycycline 100 mg capsule: modified release, 21 capsules	21	4.69	Eleuphrat
	doxycycline 100 mg capsule: modified release, 7 capsules	7	2.00	Mayne Pharma Doxycycline
	doxycycline 100 mg capsule: modified release, 7 capsules	28	8.00	Mayne Pharma Doxycycline
	doxycycline 50 mg capsule: modified release, 25 capsules	25	3.37	Mayne Pharma Doxycycline
Dulcolax	bisacodyl 10 mg suppository, 10	3	1.50	Petrus Bisacodyl Suppositories
Dulose	LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1	1	0.89	Actilax; Genlac
	LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1	3	2.67	Actilax; Genlac
Duratears	paraffin 1 g/g eye ointment, 3.5 g	2	2.54	Poly Visc
E.E.S. 200	erythromycin (as ethylsuccinate) 200 mg/5 mL oral liquid: powder for, 100 mL	1	2.71	E-Mycin 200
E.E.S. 400 Filmtab	erythromycin (as ethylsuccinate) 400 mg tablet, 25	25	2.67	E-Mycin
E.E.S. Granules	erythromycin (as ethylsuccinate) 400 mg/5 mL oral liquid: powder for, 100 mL	1	2.73	E-Mycin 400
Elocon	mometasone furoate 0.1% (1 mg/g) cream, 15 g	1	3.07	Momasone; Novasone
	mometasone furoate 0.1% lotion, 30 mL	1	3.06	Novasone; Zatamil
	mometasone furoate 0.1% ointment, 15 g	1	3.07	Novasone; Zatamil
Epilim EC	valproate sodium 200 mg tablet: enteric, 100	200	1.70	Sodium Valproate Sandoz; Valprease 200; Valpro 200; Valproate Winthrop EC 200
	valproate sodium 500 mg tablet: enteric, 100	200	1.96	Sodium Valproate Sandoz; Valprease 500; Valpro 500; Valproate Winthrop EC 500
Eryc	erythromycin 250 mg capsule: enteric, 25	25	2.91	Mayne Pharma Erythromycin
Fasigyn	tinidazole 500 mg tablet, 4	4	5.41	Simplotan
Feldene	piroxicam 10 mg capsule, 50	50	3.08	Chem mart Piroxicam; GenRx Piroxicam; Mobilis 10; Terry White Chemists Piroxicam
	piroxicam 20 mg capsule, 25	25	2.86	Chem mart Piroxicam; GenRx Piroxicam; Mobilis 20; Terry White Chemists Piroxicam
Feldene-D	piroxicam 20 mg tablet: dispersible, 25	25	3.86	Mobilis D-20
Flagyl	metronidazole 200 mg tablet, 21	21	2.30	Metrogyl 200; Metronide 200
	metronidazole 400 mg tablet, 21	21	2.30	Metrogyl 400; Metronide 400
Fosamax Plus 70 mg/140 mcg	alendronate 70 mg + colecalciferol 140 microgram tablet, 4	4	2.49	Alendronate D3 70 mg/140 microgram; Alendronate plus D3-DRLA; APO-Alendronate Plus D3 70 mg/140 mcg; Dronalen Plus; Fonat Plus
Genteal	HYPROMELLOSE Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative), 1	1	1.95	In a Wink Moisturising
Genteal gel	hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g	1	1.95	HPMC PAA
Glucophage	metformin hydrochloride 850 mg tablet, 60	60	0.56	APO-Metformin 850; Chem mart Metformin; Diabex 850; Diaformin 850; Formet Aspen 850; Glucobete 850; Metformin 850; Metformin AN; Metformin-GA; Metformin generichealth; Metformin Ranbaxy; Metformin Sandoz; Terry White Chemists Metformin
Gopten	trandolapril 1 mg capsule, 28	28	3.09	APO-Trandolapril; Dolapril 1; Tranalpha; Trandolapril-DP
	trandolapril 2 mg capsule, 28	28	3.10	APO-Trandolapril; Dolapril 2; Tranalpha; Trandolapril-DP
	trandolapril 4 mg capsule, 28	28	3.10	APO-Trandolapril; Dolapril 4; Tranalpha; Trandolapril-DP
	trandolapril 500 microgram capsule, 28	28	3.11	APO-Trandolapril; Dolapril 0.5; Tranalpha; Trandolapril-DP
Imdur 120 mg	isosorbide mononitrate 120 mg tablet: modified release, 30 tablets	30	3.03	Monodur 120 mg
Imdur Durule	isosorbide mononitrate 60 mg tablet: modified release, 30 tablets	30	3.05	Chem mart Isosorbide Mononitrate; Duride; GenRx Isosorbide Mononitrate; Imtrate 60 mg; Isomonit; Isosorbide AN; Monodur 60 mg; Terry White Chemists Isosorbide Mononitrate
Imigran	SUMATRIPTAN Tablet 50 mg (as succinate), 2	4	2.04	APO-Sumatriptan; Chem mart Sumatriptan; Iptam; Sumagran Aspen 50; Sumatab; Sumatran; Sumatriptan Sandoz; Terry

Brand Premium

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium \$	Benchmark Priced Brands
				White Chemists Sumatriptan
Imodium	loperamide hydrochloride 2 mg capsule, 12	12	0.75	Gastrex; Gastro-Stop Loperamide
Indocid	indomethacin 25 mg capsule, 50	100	4.64	Arthrexin
Isoptin	verapamil hydrochloride 80 mg tablet, 100	100	3.49	Anpec 80
Isoptin 180 SR	verapamil hydrochloride 180 mg tablet: modified release, 30 tablets	30	3.50	Cordilox 180 SR
Isoptin SR	verapamil hydrochloride 240 mg tablet: modified release, 30 tablets	30	3.50	Cordilox SR
Keflex	cephalexin 125 mg/5 mL oral liquid: powder for, 100 mL	1	4.77	APO-Cephalexin; Cefalexin Sandoz; Chem mart Cephalexin; Cilex; Ialex; Ibilex 125; Terry White Chemists Cephalexin
	cephalexin 250 mg capsule, 20	20	4.32	APO-Cephalexin; Cefalexin Sandoz; Cephalox 250; Cephalexin AN; Cephalexin generichealth; Chem mart Cephalexin; Cilex; GenRx Cephalexin; Ialex; Ibilex 250; Rancef; Terry White Chemists Cephalexin
	cephalexin 250 mg capsule, 20	40	8.64	APO-Cephalexin; Cefalexin Sandoz; Cephalox 250; Cephalexin AN; Cephalexin generichealth; Chem mart Cephalexin; Cilex; GenRx Cephalexin; Ialex; Ibilex 250; Rancef; Terry White Chemists Cephalexin
	cephalexin 250 mg/5 mL oral liquid: powder for, 100 mL	1	6.23	APO-Cephalexin; Cefalexin Sandoz; Chem mart Cephalexin; Cilex; Ialex; Ibilex 250; Terry White Chemists Cephalexin
	cephalexin 500 mg capsule, 20	20	6.31	APO-Cephalexin; Cefalexin Sandoz; Cephalox 500; Cephalexin AN; Cephalexin generichealth; Chem mart Cephalexin; Cilex; GenRx Cephalexin; Ialex; Ibilex 500; Pharmacor Cephalexin 500; Rancef; Terry White Chemists Cephalexin
Kenacomb Otic	triamcinolone acetonide 0.1% + neomycin sulfate 0.25% + gramicidin 0.025% + nystatin 100 000 international units/g ointment, 5 g	1	1.95	Otocomb Otic
	triamcinolone acetonide 0.1% + neomycin sulfate 0.25% + gramicidin 0.025% + nystatin 100 000 international units/mL ear drops, 7.5 mL	1	1.95	Otocomb Otic
Klacid	clarithromycin 250 mg tablet, 14	14	3.50	APO-Clarithromycin; Chem mart Clarithromycin; Clarac; Clarihexal; Clarithro 250; Clarithromycin AN; Clarithromycin Sandoz; Kalixocin; Terry White Chemists Clarithromycin
Lamictal	lamotrigine 100 mg tablet, 56	56	2.67	APO-Lamotrigine; GenRx Lamotrigine; Lamidus; Lamogine; Lamotrigine AN; Lamotrigine Aspen 100; Lamotrigine-GA; Lamotrigine generichealth; Lamotrigine Sandoz; Lamotrust 100; Reedos 100; Seaze 100; Torlema DT 100
	lamotrigine 200 mg tablet, 56	56	2.32	APO-Lamotrigine; GenRx Lamotrigine; Lamidus; Lamogine; Lamotrigine AN; Lamotrigine Aspen 200; Lamotrigine-GA; Lamotrigine generichealth; Lamotrigine Sandoz; Lamotrust 200; Reedos 200; Seaze 200; Torlema DT 200
	lamotrigine 25 mg tablet, 56	56	2.89	APO-Lamotrigine; GenRx Lamotrigine; Lamidus; Lamogine; Lamotrigine AN; Lamotrigine Aspen 25; Lamotrigine-GA; Lamotrigine generichealth; Lamotrigine Sandoz; Lamotrust 25; Reedos 25; Seaze 25; Torlema DT 25
	lamotrigine 5 mg tablet, 56	56	1.98	Lamogine; Lamotrigine Aspen 5; Seaze 5
	lamotrigine 50 mg tablet, 56	56	2.55	APO-Lamotrigine; GenRx Lamotrigine; Lamidus; Lamogine; Lamotrigine AN; Lamotrigine Aspen 50; Lamotrigine-GA; Lamotrigine generichealth; Lamotrigine Sandoz; Lamotrust 50; Reedos 50; Seaze 50; Torlema DT 50
Lanoxin	digoxin 250 microgram tablet, 100	100	2.94	Sigmaxin
Lanoxin-PG	digoxin 62.5 microgram tablet, 200	200	2.95	Sigmaxin-PG
Lasix	frusemide 40 mg tablet, 100	100	2.13	APO-Frusemide; Chem mart Frusemide; Frusax; Frusemide Sandoz; Frusid; GenRx Frusemide; Terry White Chemists Frusemide; Uremide
Lasix-M	frusemide 20 mg tablet, 50	100	1.68	Urex-M
Lexapro	escitalopram 10 mg tablet, 28	28	4.28	APO-Escitalopram; Chem mart Escitalopram; Cilopam-S; Escicor 10; Escitalopram AN; Escitalopram-DRLA; Escitalopram GA; Escitalopram generichealth; Esipram; Esitalo; Lexam 10; LoxaLate; Pharmacor Escitalopram 10; Terry White Chemists Escitalopram
	escitalopram 20 mg tablet, 28	28	4.95	APO-Escitalopram; Chem mart Escitalopram; Cilopam-S; Escicor 20; Escitalopram AN; Escitalopram-DRLA; Escitalopram GA; Escitalopram generichealth; Esipram; Esitalo; Lexam 20; LoxaLate; Pharmacor Escitalopram 20; Terry White Chemists Escitalopram
	escitalopram 20 mg tablet, 28	28	4.95	APO-Escitalopram; Chem mart Escitalopram; Cilopam-S; Escicor 20; Escitalopram AN; Escitalopram-DRLA; Escitalopram GA; Escitalopram generichealth; Esipram; Esitalo; Lexam 20; LoxaLate; Pharmacor Escitalopram 20; Terry White Chemists Escitalopram
Lipex 10	simvastatin 10 mg tablet, 30	30	3.33	APO-Simvastatin; Auro-Simvastatin 10; Chem mart Simvastatin; GenRx Simvastatin; Ransim; Simvacor 10; Simvar 10; Simvastatin AN; Simvastatin-DP; Simvastatin-DRLA; Simvastatin-GA 10; Simvastatin generichealth; Simvastatin Sandoz; Terry White Chemists Simvastatin; Zimstat; Zocor

Brand Premium

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium \$	Benchmark Priced Brands
Lipex 20	simvastatin 20 mg tablet, 30	30	3.33	APO-Simvastatin; Auro-Simvastatin 20; Chem mart Simvastatin; Ransim; Simvacor 20; Simvar 20; Simvastatin AN; Simvastatin-DP; Simvastatin-DRLA; Simvastatin-GA 20; Simvastatin generichealth; Simvastatin Sandoz; Terry White Chemists Simvastatin; Zimstat; Zocor
Lipex 40	simvastatin 40 mg tablet, 30	30	3.33	APO-Simvastatin; Auro-Simvastatin 40; Chem mart Simvastatin; Ransim; Simvacor 40; Simvar 40; Simvastatin AN; Simvastatin-DP; Simvastatin-DRLA; Simvastatin-GA 40; Simvastatin generichealth; Simvastatin Sandoz; Terry White Chemists Simvastatin; Zimstat; Zocor
Lipex 80	simvastatin 80 mg tablet, 30	30	3.33	APO-Simvastatin; Auro-Simvastatin 80; Chem mart Simvastatin; Ransim; Simvacor 80; Simvar 80; Simvastatin AN; Simvastatin-DP; Simvastatin-DRLA; Simvastatin-GA 80; Simvastatin generichealth; Simvastatin Sandoz; Terry White Chemists Simvastatin; Zimstat; Zocor
Liquifilm Tears	polyvinyl alcohol 1.4% eye drops, 15 mL	1	1.60	PVA Tears
Lomotil	diphenoxylate hydrochloride 2.5 mg + atropine sulfate 25 microgram tablet, 20	20	1.73	Lofenoxal
Lopresor 100	METOPROLOL TARTRATE Tablet 100 mg, 60	60	2.00	Metatar; Metoprolol Actavis; Metoprolol AN; Mistrom
Lopresor 50	METOPROLOL TARTRATE Tablet 50 mg, 100	100	2.01	Metatar; Metoprolol Actavis; Metoprolol AN; Mistrom
Losec Tablets	omeprazole 20 mg tablet: enteric, 30 tablets	30	2.48	Acimax Tablets; Omepral; Omeprazole Sandoz
Luvox	fluvoxamine maleate 100 mg tablet, 30	30	3.10	APO-Fluvoxamine; Faverin 100; Fluvoxamine GA; Movox 100; Voxam
	fluvoxamine maleate 50 mg tablet, 30	30	3.11	APO-Fluvoxamine; Faverin 50; Fluvoxamine GA; Movox 50; Voxam
Maxamox	amoxycillin 1 g tablet, 14	14	0.41	Amoxycillin Sandoz
Maxolon	metoclopramide hydrochloride 10 mg tablet, 25	25	2.54	APO-Metoclopramide; Metoclopramide Actavis; Metoclopramide AN
Mayne Pharma Doxycycline	doxycycline 100 mg capsule: modified release, 21 capsules	21	1.93	Doryx
	doxycycline 100 mg capsule: modified release, 7 capsules	7	0.84	Doryx
	doxycycline 100 mg capsule: modified release, 7 capsules	28	3.36	Doryx
	doxycycline 50 mg capsule: modified release, 25 capsules	25	1.40	Doryx
Microgynon 30 ED	ethinyloestradiol 30 microgram + levonorgestrel 150 microgram tablet [84] (&) inert substance tablet [28], 112 [4 x 28]	4	11.41	Eleanor 150/30 ED; Evelyn 150/30 ED; Femme-Tab ED 30/150; Levlen ED; Micronelle 30 ED
Minidiab	glipizide 5 mg tablet, 100	100	4.51	Melizide
Minomycin-50	minocycline 50 mg tablet, 60	60	1.89	Akamin 50
Mobic	meloxicam 15 mg capsule, 30	30	2.08	APO-Meloxicam; Chem mart Meloxicam; Melox 15; Movalis 15; Terry White Chemists Meloxicam
	meloxicam 15 mg tablet, 30	30	2.08	APO-Meloxicam; Chem mart Meloxicam 15 mg; GenRx Meloxicam; Meloxiauro 15; Meloxibell; Meloxicam AN; Meloxicam-GA; Meloxicam Ranbaxy; Meloxicam Sandoz; Movalis 15; Moxicam 15; Pharmacor Meloxicam 15; Terry White Chemists Meloxicam 15 mg
	meloxicam 7.5 mg capsule, 30	30	2.09	APO-Meloxicam; Chem mart Meloxicam; Melox 7.5; Movalis 7.5; Terry White Chemists Meloxicam
	meloxicam 7.5 mg tablet, 30	30	2.09	APO-Meloxicam; Chem mart Meloxicam 7.5 mg; GenRx Meloxicam; Meloxiauro 7.5; Meloxibell; Meloxicam AN; Meloxicam-GA; Meloxicam Ranbaxy; Meloxicam Sandoz; Movalis 7.5; Moxicam 7.5; Pharmacor Meloxicam 7.5; Terry White Chemists Meloxicam 7.5 mg
Mogadon	nitrazepam 5 mg tablet, 25	25	1.24	Alodorm
	nitrazepam 5 mg tablet, 25	50	2.48	Alodorm
Monodur 60 mg	isosorbide mononitrate 60 mg tablet: modified release, 30 tablets	30	2.23	Chem mart Isosorbide Mononitrate; Duride; GenRx Isosorbide Mononitrate; Imdur Durule; Imtrate 60 mg; Isomonit; Isosorbide AN; Terry White Chemists Isosorbide Mononitrate
Naprosyn	naproxen 250 mg tablet, 50	100	2.24	Inza 250
	naproxen 500 mg tablet, 50	50	1.28	Inza 500
Naprosyn SR1000	naproxen 1 g tablet: modified release, 28	28	1.29	Proxen SR 1000
Naprosyn SR750	naproxen 750 mg tablet: modified release, 28 tablets	28	1.22	Proxen SR 750
Natrilix	indapamide hemihydrate 2.5 mg tablet, 90	90	4.11	Chem mart Indapamide; Dapa-Tabs; GenRx Indapamide; Indapamide AN; Indapamide-GA; Indapamide Sandoz; Insig; Terry White Chemists Indapamide
Nilstat	nystatin 100 000 international units/mL oral liquid, 24 mL	1	3.01	Mycostatin
Nordette 28	ethinyloestradiol 30 microgram + levonorgestrel 150	4	14.37	Monofeme 28

Brand Premium

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium \$	Benchmark Priced Brands
	microgram tablet [84] (&) inert substance tablet [28], 112 [4 x 28]			
Normison	temazepam 10 mg tablet, 25	25	4.00	APO-Temazepam; Temaze; Temtabs
	temazepam 10 mg tablet, 25	50	8.00	APO-Temazepam; Temaze; Temtabs
Norvasc	amlodipine 10 mg tablet, 30	30	6.82	Amlo 10; Amlodipine AN; Amlodipine-DRLA; Amlodipine generichealth; Amlodipine Sandoz; APO-Amlodipine; Auro-Amlodipine 10; Chem mart Amlodipine; Nordip; Norvapine; Ozlodip; Pharmacor Amlodipine; Terry White Chemists Amlodipine
	amlodipine 5 mg tablet, 30	30	4.61	Amlo 5; Amlodipine AN; Amlodipine-DRLA; Amlodipine generichealth; Amlodipine Sandoz; APO-Amlodipine; Auro-Amlodipine 5; Chem mart Amlodipine; Nordip; Norvapine; Ozlodip; Pharmacor Amlodipine; Terry White Chemists Amlodipine
Oroxine	thyroxine sodium 100 microgram tablet, 200	200	2.21	Eutroxsig
	thyroxine sodium 200 microgram tablet, 200	200	2.21	Eutroxsig
	thyroxine sodium 50 microgram tablet, 200	200	2.20	Eutroxsig
	thyroxine sodium 75 microgram tablet, 200	200	2.27	Eutroxsig
Orudis SR 200	ketoprofen 200 mg capsule: modified release, 28 capsules	28	2.21	Oruvail SR
Panadeine Forte	CODEINE PHOSPHATE with PARACETAMOL Tablet 30 mg-500 mg, 20	20	2.40	APO- Paracetamol/Codeine 500/30; Codalgin Forte; Codapane Forte; Comfarol Forte; Paracetamol/Codeine GH 500/30; Prodeine Forte
	CODEINE PHOSPHATE with PARACETAMOL Tablet 30 mg-500 mg, 20	60	7.20	APO- Paracetamol/Codeine 500/30; Codalgin Forte; Codapane Forte; Comfarol Forte; Paracetamol/Codeine GH 500/30; Prodeine Forte
Panadol Osteo	paracetamol 665 mg tablet: modified release, 96 tablets	192	1.64	Osteomol 665 Paracetamol
Panafcort	prednisone 1 mg tablet, 100	100	0.91	Predsone
Panafcortelone	prednisolone 1 mg tablet, 100	100	0.82	Predsolone
Plendil ER	felodipine 10 mg tablet: modified release, 30 tablets	30	2.76	Felodil XR 10; Felodur ER 10 mg; Fendex ER
	felodipine 2.5 mg tablet: modified release, 30 tablets	30	2.75	Felodur ER 2.5 mg; Fendex ER
	felodipine 5 mg tablet: modified release, 30 tablets	30	2.76	Felodil XR 5; Felodur ER 5 mg; Fendex ER
Pravachol	pravastatin sodium 10 mg tablet, 30	30	1.38	APO-Pravastatin; Auro-Pravastatin 10; Chem mart Pravastatin; Cholstat 10; Lipostat 10; Pharmacor Pravastat 10; Pravastatin Actavis 10; Pravastatin AN; Pravastatin-GA 10; Pravastatin generichealth; Pravastatin Sandoz; Terry White Chemists Pravastatin
	pravastatin sodium 20 mg tablet, 30	30	1.37	APO-Pravastatin; Auro-Pravastatin 20; Chem mart Pravastatin; Cholstat 20; Cholvastin; Lipostat 20; Pharmacor Pravastat 20; Pravastatin Actavis 20; Pravastatin AN; Pravastatin-GA 20; Pravastatin generichealth; Pravastatin Sandoz; Terry White Chemists Pravastatin
	pravastatin sodium 40 mg tablet, 30	30	1.46	APO-Pravastatin; Auro-Pravastatin 40; Chem mart Pravastatin; Cholstat 40; Cholvastin; Lipostat 40; Pharmacor Pravastat 40; Pravastatin Actavis 40; Pravastatin AN; Pravastatin-GA 40; Pravastatin generichealth; Pravastatin Sandoz; Terry White Chemists Pravastatin
	pravastatin sodium 80 mg tablet, 30	30	1.46	APO-Pravastatin; Auro-Pravastatin 80; Chem mart Pravastatin; Lipostat 80; Pravastatin AN; Pravastatin-GA 80; Pravastatin generichealth; Pravastatin Sandoz; Terry White Chemists Pravastatin
PREXUM 2.5	perindopril arginine 2.5 mg tablet, 30	30	1.65	Coversyl 2.5mg
Prinivil 10	lisinopril 10 mg tablet, 30	30	3.21	APO-Lisinopril; Auro-Lisinopril 10; Chem mart Lisinopril; Fibsol 10; Lisinopril AN; Lisinopril-DRLA; Lisinopril-GA; Lisinopril generichealth; Lisinopril Sandoz; Terry White Chemists Lisinopril; Zestril; Zinopril 10
Prinivil 20	lisinopril 20 mg tablet, 30	30	3.21	APO-Lisinopril; Auro-Lisinopril 20; Chem mart Lisinopril; Fibsol 20; Lisinopril AN; Lisinopril-DRLA; Lisinopril-GA; Lisinopril generichealth; Lisinopril Sandoz; Terry White Chemists Lisinopril; Zestril; Zinopril 20
Provera	medroxyprogesterone acetate 10 mg tablet, 100	100	2.53	Ralovera
	medroxyprogesterone acetate 10 mg tablet, 30	30	2.46	Ralovera
	medroxyprogesterone acetate 5 mg tablet, 56	56	2.59	Ralovera
Prozac 20	fluoxetine 20 mg capsule, 28	28	1.78	Auscasp Aspen; Chem mart Fluoxetine; Fluoxetine 20; Fluoxetine AN; Fluoxetine-GA; Fluoxetine generichealth; Fluoxetine RBX; Fluoxetine Sandoz; GenRx Fluoxetine; Lovan; Terry White Chemists Fluoxetine; Zactin
Prozac Tab	fluoxetine 20 mg tablet: dispersible, 28	28	1.78	Lovan 20 Tab; Zactin Tablet
Redipred	prednisolone (as sodium phosphate) 5 mg/mL oral liquid, 30 mL	1	2.70	PredMix
Refresh Night	paraffin 1 g/g eye ointment, 2 x 3.5 g tubes	1	2.12	Ircal

Brand Premium

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium \$	Benchmark Priced Brands
Time				
Renitec	enalapril maleate 10 mg tablet, 30	30	4.07	Acetec; APO-Enalapril; Auspril; Chem mart Enalapril; Enalapril Actavis; Enalapril AN; Enalapril-GA; Enalapril generichealth; Enalapril Sandoz; GenRx Enalapril; Malean; Terry White Chemists Enalapril
Renitec 20	enalapril maleate 20 mg tablet, 30	30	4.05	Acetec; APO-Enalapril; Auspril; Chem mart Enalapril; Enalapril Actavis; Enalapril AN; Enalapril-GA; Enalapril generichealth; Enalapril Sandoz; GenRx Enalapril; Malean; Terry White Chemists Enalapril
Rivotril	clonazepam 2 mg tablet, 100	100	1.93	Paxam 2
	clonazepam 2 mg tablet, 100	200	3.86	Paxam 2
	clonazepam 500 microgram tablet, 100	100	1.71	Paxam 0.5
	clonazepam 500 microgram tablet, 100	200	3.42	Paxam 0.5
Rulide	roxithromycin 150 mg tablet, 10	10	2.12	APO-Roxithromycin; Biaxsig; Chem mart Roxithromycin; Roxar 150; Roximycin; Roxithromycin AN; Roxithromycin-GA; Roxithromycin GH; Roxithromycin Sandoz; Roxithromycin SCP 150; Terry White Chemists Roxithromycin
	roxithromycin 300 mg tablet, 5	5	2.12	APO-Roxithromycin; Biaxsig; Chem mart Roxithromycin; Roxar 300; Roximycin; Roxithromycin AN; Roxithromycin-GA; Roxithromycin GH; Roxithromycin Sandoz; Roxithromycin SCP 300; Terry White Chemists Roxithromycin
Salazopyrin-EN	SULFASALAZINE Tablet 500 mg (enteric coated), 100	200	2.48	Pyralin EN
Septtrin Forte	trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10	10	3.90	Bactrim DS; Resprim Forte
Serepax	oxazepam 15 mg tablet, 25	25	2.68	Alepam 15
	oxazepam 15 mg tablet, 25	50	5.36	Alepam 15
	oxazepam 30 mg tablet, 25	25	2.68	Alepam 30; APO-Oxazepam; Murelax
	oxazepam 30 mg tablet, 25	50	5.36	Alepam 30; APO-Oxazepam; Murelax
Sigmacort	hydrocortisone acetate 1% (10 mg/g) cream, 30 g	1	2.69	Cortic-DS 1%
	hydrocortisone acetate 1% (10 mg/g) cream, 50 g	1	2.70	Cortic-DS 1%
	hydrocortisone acetate 1% (10 mg/g) ointment, 30 g	1	2.69	Cortic-DS 1%
	hydrocortisone acetate 1% (10 mg/g) ointment, 50 g	1	2.70	Cortic-DS 1%
Sinemet 100/25	levodopa 100 mg + carbidopa anhydrous 25 mg tablet, 100	100	5.19	Kinson
Slow-K	potassium chloride 600 mg (8 mmol potassium) tablet: modified release, 100 tablets	200	2.94	Duro-K
Sofradex	dexamethasone 0.05% (500 microgram/mL) + framycetin sulfate 0.5% (5 mg/mL) + gramicidin 0.005% (50 microgram/mL) ear drops, 8 mL	1	1.91	Otodex
Sotacor	sotalol hydrochloride 160 mg tablet, 60	60	3.32	APO-Sotalol; Cardol; Chem mart Sotalol; GenRx Sotalol; Solavert; Sotalol Sandoz; Terry White Chemists Sotalol
	sotalol hydrochloride 80 mg tablet, 60	60	3.31	APO-Sotalol; GenRx Sotalol; Solavert; Sotalol Sandoz
Stemetil	prochlorperazine maleate 5 mg tablet, 25	25	2.70	APO-Prochlorperazine; Pharmacor Prozine 5; ProCalm; Prochlorperazine AN; Prochlorperazine-GA; Prochlorperazine GH; Stemizine
Tazac	nizatidine 150 mg capsule, 60	60	5.32	Nizac; Tacidine
	nizatidine 300 mg capsule, 30	30	5.32	Nizac; Tacidine
Tears Naturale	dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL	1	2.04	Poly-Tears
Tegretol 100	CARBAMAZEPINE Tablet 100 mg, 100	200	2.96	Carbamazepine Sandoz
Tegretol 200	CARBAMAZEPINE Tablet 200 mg, 100	200	2.96	Carbamazepine Sandoz
Tenormin	atenolol 50 mg tablet, 30	30	1.96	APO-Atenolol; Atenolol AN; Atenolol-GA; Atenolol GH; Atenolol Sandoz; Chem mart Atenolol; Noten; Tenolten 50; Tensig; Terry White Chemists Atenolol
Timoptol	timolol 0.5% (5 mg/mL) eye drops, 5 mL	1	3.03	Tenopt
Tofranil 10	imipramine hydrochloride 10 mg tablet, 50	50	2.79	Tolerade 10
Tofranil 25	imipramine hydrochloride 25 mg tablet, 50	50	2.78	Tolerade 25
Tramal	tramadol hydrochloride 50 mg capsule, 20	20	2.05	APO-Tramadol; Chem mart Tramadol; GA Tramadol 50mg; Terry White Chemists Tramadol; Tramadol Actavis; Tramadol AN; Tramadol Sandoz; Tramadol SCP; Tramedo; Zydol
Tramal SR 100	tramadol hydrochloride 100 mg tablet: modified release, 20 tablets	20	3.83	APO-Tramadol SR; Chem mart Tramadol SR; GA Tramadol SR 100mg; Lodam SR 100; Terry White Chemists Tramadol SR; Tramadol AN SR; Tramadol Sandoz SR; Tramadol SR generichealth; Tramedo SR 100; Zydol SR 100
Tramal SR 150	tramadol hydrochloride 150 mg tablet: modified release, 20 tablets	20	4.58	APO-Tramadol SR; Chem mart Tramadol SR; GA Tramadol SR 150mg; Lodam SR 150; Terry White Chemists Tramadol SR; Tramadol AN SR; Tramadol Sandoz SR; Tramadol SR generichealth; Tramedo SR 150; Zydol SR 150
Tramal SR 200	tramadol hydrochloride 200 mg tablet: modified release, 20 tablets	20	5.20	APO-Tramadol SR; Chem mart Tramadol SR; GA Tramadol SR 200mg; Terry White Chemists Tramadol SR; Tramadol AN SR; Tramadol Sandoz SR; Tramadol SR generichealth;

Brand Premium

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium \$	Benchmark Priced Brands
				Tramedo SR 200; Zydol SR 200
Trandate	labetalol hydrochloride 100 mg tablet, 100	100	3.13	Presolol 100
	labetalol hydrochloride 200 mg tablet, 100	100	3.14	Presolol 200
Triphasil 28	ethinylloestradiol 30 microgram + levonorgestrel 50 microgram tablet [24] (&) ethinylloestradiol 40 microgram + levonorgestrel 75 microgram tablet [20] (&) ethinylloestradiol 30 microgram + levonorgestrel 125 microgram tablet [40] (&) inert substance tablet [28], 112 [4 x 28]	4	14.37	Trifeme 28
Triprim	trimethoprim 300 mg tablet, 7	7	1.89	Alprim
	trimethoprim 300 mg tablet, 7	14	3.78	Alprim
Triquilar ED	ethinylloestradiol 30 microgram + levonorgestrel 50 microgram tablet [24] (&) ethinylloestradiol 40 microgram + levonorgestrel 75 microgram tablet [20] (&) ethinylloestradiol 30 microgram + levonorgestrel 125 microgram tablet [40] (&) inert substance tablet [28], 112 [4 x 28]	4	11.41	Logynon ED
Valium	diazepam 5 mg tablet, 50	50	2.52	Antenex 5; APO-Diazepam; Ranzepam; Valpam 5
Vastin	fluvastatin 20 mg capsule, 28	28	3.09	Lescol
	fluvastatin 40 mg capsule, 28	28	3.38	Lescol
Ventolin CFC-free	salbutamol 100 microgram/actuation inhalation: pressurised, 200	2	2.34	APO-Salbutamol Inhaler; Asmol CFC-free
Ventolin Nebules	salbutamol 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules	2	1.20	APO-Salbutamol; Asmol 2.5 uni-dose; Butamol 2.5; GenRx Salbutamol; Pharmacor Salbutamol 2.5; Salbutamol Actavis; Salbutamol-GA; Salbutamol Sandoz
	salbutamol 5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules	2	1.16	APO-Salbutamol; Asmol 5 uni-dose; Butamol 5; GenRx Salbutamol; Pharmacor Salbutamol 5; Salbutamol Actavis; Salbutamol-GA; Salbutamol Sandoz
Viscotears	carbomer-980 0.2% eye gel, 10 g	1	1.84	Optifresh eye gel; PAA
Voltaren 25	diclofenac sodium 25 mg tablet: enteric, 50 tablets	100	1.44	APO-Diclofenac; Chem mart Diclofenac; Clonac 25; Diclofenac AN; Diclofenac-GA; Diclofenac Sandoz; Fenac 25; Terry White Chemists Diclofenac
Voltaren 50	diclofenac sodium 50 mg tablet: enteric, 50 tablets	50	1.43	APO-Diclofenac; Chem mart Diclofenac; Clonac 50; Diclofenac AN; Diclofenac-GA; Diclofenac Sandoz; Fenac; Terry White Chemists Diclofenac
Zanidip	lercanidipine hydrochloride 10 mg tablet, 28	28	2.98	APO-Lercanidipine; Chem mart Lercanidipine; Ledip; Lercadip; Lercan; Lercanidipine GH; Lercanidipine Sandoz; Terry White Chemists Lercanidipine; Zircol
	lercanidipine hydrochloride 20 mg tablet, 28	28	2.97	APO-Lercanidipine; Chem mart Lercanidipine; Ledip; Lercadip; Lercan; Lercanidipine GH; Lercanidipine Sandoz; Terry White Chemists Lercanidipine; Zircol
Zantac	ranitidine 150 mg tablet, 60	60	1.15	APO-Ranitidine; Ausran; Chem mart Ranitidine; GenRx Ranitidine; Rani 2; Ranitidine AN; Ranitidine Sandoz; Ranoxyl; Terry White Chemists Ranitidine; Ulcaid
	ranitidine 300 mg tablet, 30	30	1.15	APO-Ranitidine; Ausran; Chem mart Ranitidine; GenRx Ranitidine; Rani 2; Ranitidine GH; Ranitidine Sandoz; Ranoxyl; Terry White Chemists Ranitidine
Zestril	lisinopril 10 mg tablet, 30	30	2.82	APO-Lisinopril; Auro-Lisinopril 10; Chem mart Lisinopril; Fibsol 10; Lisinopril AN; Lisinopril-DRLA; Lisinopril-GA; Lisinopril generichealth; Lisinopril Sandoz; Prinivil 10; Terry White Chemists Lisinopril; Zinopril 10
	lisinopril 20 mg tablet, 30	30	2.81	APO-Lisinopril; Auro-Lisinopril 20; Chem mart Lisinopril; Fibsol 20; Lisinopril AN; Lisinopril-DRLA; Lisinopril-GA; Lisinopril generichealth; Lisinopril Sandoz; Prinivil 20; Terry White Chemists Lisinopril; Zinopril 20
	lisinopril 5 mg tablet, 30	30	2.82	APO-Lisinopril; Auro-Lisinopril 5; Chem mart Lisinopril; Fibsol 5; Lisinopril AN; Lisinopril-DRLA; Lisinopril-GA; Lisinopril generichealth; Lisinopril Sandoz; Terry White Chemists Lisinopril; Zinopril 5
Zocor	simvastatin 10 mg tablet, 30	30	3.33	APO-Simvastatin; Auro-Simvastatin 10; Chem mart Simvastatin; GenRx Simvastatin; Lipex 10; Ransim; Simvacor 10; Simvar 10; Simvastatin AN; Simvastatin-DP; Simvastatin-DRLA; Simvastatin-GA 10; Simvastatin generichealth; Simvastatin Sandoz; Terry White Chemists Simvastatin; Zimstat
	simvastatin 20 mg tablet, 30	30	3.33	APO-Simvastatin; Auro-Simvastatin 20; Chem mart Simvastatin; Lipex 20; Ransim; Simvacor 20; Simvar 20; Simvastatin AN; Simvastatin-DP; Simvastatin-DRLA; Simvastatin-GA 20; Simvastatin generichealth; Simvastatin Sandoz; Terry White Chemists Simvastatin; Zimstat
	simvastatin 40 mg tablet, 30	30	3.33	APO-Simvastatin; Auro-Simvastatin 40; Chem mart Simvastatin; Lipex 40; Ransim; Simvacor 40; Simvar 40;

Brand Premium

Premium Priced Brand	Form and Strength	Max. Qty	Brand Premium \$	Benchmark Priced Brands
	simvastatin 80 mg tablet, 30	30	3.33	Simvastatin AN; Simvastatin-DP; Simvastatin-DRLA; Simvastatin-GA 40; Simvastatin generichealth; Simvastatin Sandoz; Terry White Chemists Simvastatin; Zimstat APO-Simvastatin; Auro-Simvastatin 80; Chem mart Simvastatin; Lipex 80; Ransim; Simvacor 80; Simvar 80; Simvastatin AN; Simvastatin-DP; Simvastatin-DRLA; Simvastatin-GA 80; Simvastatin generichealth; Simvastatin Sandoz; Terry White Chemists Simvastatin; Zimstat
Zoloft	sertraline 100 mg tablet, 30	30	0.59	APO-Sertraline; Auro-Sertraline 100; Chem mart Sertraline; Eleva 100; GenRx Sertraline; Sertra 100; Sertracor 100; Sertraline Actavis; Sertraline AN; Sertraline-DRLA; Sertraline generichealth; Sertraline Sandoz; Setrona; Terry White Chemists Sertraline; Xydep 100
	sertraline 50 mg tablet, 30	30	0.59	APO-Sertraline; Auro-Sertraline 50; Chem mart Sertraline; Eleva 50; GenRx Sertraline; Sertra 50; Sertracor 50; Sertraline Actavis; Sertraline AN; Sertraline-DRLA; Sertraline generichealth; Sertraline Sandoz; Setrona; Terry White Chemists Sertraline; Xydep 50
Zomig	zolmitriptan 2.5 mg tablet, 2	4	2.76	APO-Zolmitriptan; Zoltrip
Zovirax 200 mg	aciclovir 200 mg tablet, 25	50	2.06	Acihexal; Acyclo-V 200; Lovir
	aciclovir 200 mg tablet, 90	90	1.49	Aciclovir 200; Aciclovir GH; Acyclo-V 200; Chem mart Aciclovir; GenRx Aciclovir; Lovir; Ozvir; Terry White Chemists Aciclovir
Zovirax 800 mg	aciclovir 800 mg tablet, 35	35	0.80	Aciclovir 800; Acihexal; Acyclo-V 800; GenRx Aciclovir
Zyban	bupropion hydrochloride 150 mg tablet: modified release, 30 tablets	30	0.80	Prexaton
	bupropion hydrochloride 150 mg tablet: modified release, 90 tablets	90	0.96	Prexaton
Zyloprim	allopurinol 100 mg tablet, 200	200	3.99	Allopurinol Sandoz; Allosig; APO-Allopurinol; Chem mart Allopurinol; GenRx Allopurinol; Terry White Chemists Allopurinol
	allopurinol 300 mg tablet, 60	60	4.00	Allopurinol Sandoz; Allosig; APO-Allopurinol; Chem mart Allopurinol; GenRx Allopurinol; Progout 300; Terry White Chemists Allopurinol