



Australian Government

Department of Health



Schedule of Pharmaceutical Benefits

Summary of Changes

Effective 1 June 2016



Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 June 2016 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	\$6.93
	Dangerous drug fee	\$2.91
	Extemporaneously-prepared	\$8.97
	Allowable additional patient charge*	\$4.33
Additional Fees (for safety net prices):	Ready-prepared	\$1.17
	Extemporaneously-prepared	\$1.53
Patient Co-payments:	General	\$38.30
	Concessional	\$6.20
Safety Net Thresholds:	General	\$1475.70
	Concessional	\$372.00
Safety Net Card Issue Fee:		\$9.61

* 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.

Summary of Changes

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 June 2016. The Schedule is updated on the first day of each month and is available on the internet at www.pbs.gov.au.

Prescriber Bag

Additions

Addition – Item

10786Q **NALOXONE**, naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules (*Naloxone Hydrochloride (DBL)*)

Deletions

Deletion – Item

2200T **NALOXONE**, naloxone hydrochloride 400 microgram/mL injection, 1 x 1 mL syringe (*Naloxone minijet*)

Deletion – Brand

3495Y *APO-Salbutamol Inhaler, TX* – **SALBUTAMOL**, salbutamol 100 microgram/actuation inhalation: pressurised, 200 actuations

General Pharmaceutical Benefits

Additions

Addition – Item

- 10778G **CEPHALEXIN**, cephalexin 500 mg capsule, 20 (*APO-Cephalexin, Cefalexin Sandoz, Cephalex 500, Cephalexin AN, Cephalexin generichealth, Chem mart Cephalexin, Cilex, Ialex, Ibilex 500, Keflex, Rancef, Terry White Chemists Cephalexin*)
- 10790X **DICLOXACILLIN**, dicloxacillin 500 mg capsule, 24 (*Distaph 500*)
- 10777F **DOXYCYCLINE**, doxycycline 100 mg capsule: modified release, 7 (*Doryx, Mayne Pharma Doxycycline*)
- 10779H **DOXYCYCLINE**, doxycycline 100 mg tablet, 7 (*Doxsig, Doxy-100, Doxycycline AN, Doxylin 100*)
- 10781K **DOXYCYCLINE**, doxycycline 100 mg tablet, 7 (*Chem mart Doxycycline, Doxycycline Sandoz, GenRx Doxycycline, Terry White Chemists Doxycycline*)
- 10780J **ERYTHROMYCIN**, erythromycin 250 mg capsule: enteric, 25 (*Eryc, Mayne Pharma Erythromycin*)
- 10789W **ERYTHROMYCIN ETHYLSUCCINATE**, erythromycin (as ethylsuccinate) 400 mg tablet, 25 (*E-Mycin, E.E.S. 400 Filmstab*)
- 10788T **FLUCLOXACILLIN**, flucloxacillin 500 mg capsule, 24 (*APO-Flucloxacillin, Flopen, Staphylex 500*)
- 10782L **FUSIDATE**, fusidate sodium 250 mg tablet, 36 (*Fucidin*)
- 10783M **NALOXONE**, naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules (*Naloxone Hydrochloride (DBL)*)

- 10787R **NALOXONE**, naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules (*Naloxone Hydrochloride (DBL)*) **(Dental)**
- 10785P **TRIMETHOPRIM**, trimethoprim 300 mg tablet, 7 (*Alprim, Triprim*)
- 10784N **TRIMETHOPRIM + SULFAMETHOXAZOLE**, trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10 (*Bactrim DS, Resprim Forte, Seprin Forte*)

Addition – Brand

- 8188Y *Acarbose Mylan, AF* – **ACARBOSE**, acarbose 50 mg tablet, 90
- 8189B *Acarbose Mylan, AF* – **ACARBOSE**, acarbose 100 mg tablet, 90
- 8358X *Blooms the Chemist Clopidogrel, IB* – **CLOPIDOGREL**, clopidogrel 75 mg tablet, 28
- 9317J *Blooms the Chemist Clopidogrel, IB* – **CLOPIDOGREL**, clopidogrel 75 mg tablet, 28
- 9317J *Chem mart Clopidogrel, CH* – **CLOPIDOGREL**, clopidogrel 75 mg tablet, 28
- 9317J *Terry White Chemists Clopidogrel, TW* – **CLOPIDOGREL**, clopidogrel 75 mg tablet, 28
- 8879H *Inpler, AF* – **EPLERENONE**, eplerenone 25 mg tablet, 30
- 8880J *Inpler, AF* – **EPLERENONE**, eplerenone 50 mg tablet, 30
- 5470X *Ondansetron ODT GH, GQ* – **ONDANSETRON**, ONDANSETRON Tablet (orally disintegrating) 4 mg, 4
- 5472B *Ondansetron ODT GH, GQ* – **ONDANSETRON**, ONDANSETRON Tablet (orally disintegrating) 4 mg, 10
- 5471Y *Ondansetron ODT GH, GQ* – **ONDANSETRON**, ONDANSETRON Tablet (orally disintegrating) 8 mg, 4
- 5473C *Ondansetron ODT GH, GQ* – **ONDANSETRON**, ONDANSETRON Tablet (orally disintegrating) 8 mg, 10
- 9203J *QUETIAPINE-AS XR, RW* – **QUETIAPINE**, quetiapine 200 mg tablet: modified release, 60
- 9204K *QUETIAPINE-AS XR, RW* – **QUETIAPINE**, quetiapine 300 mg tablet: modified release, 60
- 9205L *QUETIAPINE-AS XR, RW* – **QUETIAPINE**, quetiapine 400 mg tablet: modified release, 60
- 9391G *ATELVIA ONCE-A-MONTH, GN* – **RISEDRONATE**, risedronate sodium 150 mg tablet, 1

Addition – Equivalence Indicator

- 8188Y *Glucobay 50, BN* – **ACARBOSE**, acarbose 50 mg tablet, 90
- 8189B *Glucobay 100, BN* – **ACARBOSE**, acarbose 100 mg tablet, 90
- 8879H *Inspra, PF* – **EPLERENONE**, eplerenone 25 mg tablet, 30
- 8880J *Inspra, PF* – **EPLERENONE**, eplerenone 50 mg tablet, 30
- 9203J *Seroquel XR, AP* – **QUETIAPINE**, quetiapine 200 mg tablet: modified release, 60
- 9204K *Seroquel XR, AP* – **QUETIAPINE**, quetiapine 300 mg tablet: modified release, 60
- 9205L *Seroquel XR, AP* – **QUETIAPINE**, quetiapine 400 mg tablet: modified release, 60
- 1937Y *Zantac, AS* – **RANITIDINE**, ranitidine 150 mg tablet: effervescent, 30

Deletions

Deletion – Item

- 9195Y **ENOXAPARIN SODIUM**, enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL ampoules (*Clexane*)
- 9196B **ENOXAPARIN SODIUM**, enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL ampoules (*Clexane*)
- 1588N **KETOPROFEN**, ketoprofen 100 mg suppository, 20 (*Orudis*)
- 5139L **KETOPROFEN**, ketoprofen 100 mg suppository, 20 (*Orudis*) **(Dental)**
- 2192J **NALOXONE**, naloxone hydrochloride 400 microgram/mL injection, 1 x 1 mL syringe (*Naloxone minijet*)
- 2196N **NALOXONE**, naloxone hydrochloride 400 microgram/mL injection, 1 x 1 mL syringe (*Naloxone minijet*) **(Dental)**

Deletion – Brand

8511Y	Chem mart Alendronate 70mg, CH – ALENDRONATE , alendronate 70 mg tablet, 4
8511Y	Terry White Chemists Alendronate 70mg, TW – ALENDRONATE , alendronate 70 mg tablet, 4
2390T	Ibimicyn, JU – AMPICILLIN , ampicillin 500 mg injection, 5 vials
3313J	Ibimicyn, JU – AMPICILLIN , ampicillin 500 mg injection, 5 vials (Dental)
2977Q	Ibimicyn, JU – AMPICILLIN , ampicillin 1 g injection, 5 vials
3314K	Ibimicyn, JU – AMPICILLIN , ampicillin 1 g injection, 5 vials (Dental)
1312C	Chem mart Diltiazem CD, CH – DILTIAZEM , diltiazem hydrochloride 180 mg capsule: modified release, 30
1312C	GenRx Diltiazem CD, GX – DILTIAZEM , diltiazem hydrochloride 180 mg capsule: modified release, 30
1312C	Terry White Chemists Diltiazem CD, TW – DILTIAZEM , diltiazem hydrochloride 180 mg capsule: modified release, 30
1313D	Chem mart Diltiazem CD, CH – DILTIAZEM , diltiazem hydrochloride 240 mg capsule: modified release, 30
1313D	GenRx Diltiazem CD, GX – DILTIAZEM , diltiazem hydrochloride 240 mg capsule: modified release, 30
1313D	Terry White Chemists Diltiazem CD, TW – DILTIAZEM , diltiazem hydrochloride 240 mg capsule: modified release, 30
1524F	Flucil, AS – FLUCLOXACILLIN , flucloxacillin 500 mg injection, 5 vials
5094D	Flucil, AS – FLUCLOXACILLIN , flucloxacillin 500 mg injection, 5 vials (Dental)
1453L	Chem mart Gemfibrozil, CH – GEMFIBROZIL , gemfibrozil 600 mg tablet, 60
1453L	GenRx Gemfibrozil, GX – GEMFIBROZIL , gemfibrozil 600 mg tablet, 60
1453L	Terry White Chemists Gemfibrozil, TW – GEMFIBROZIL , gemfibrozil 600 mg tablet, 60
9248R	Chem mart Gemfibrozil, CH – GEMFIBROZIL , gemfibrozil 600 mg tablet, 60
9248R	GenRx Gemfibrozil, GX – GEMFIBROZIL , gemfibrozil 600 mg tablet, 60
9248R	Terry White Chemists Gemfibrozil, TW – GEMFIBROZIL , gemfibrozil 600 mg tablet, 60
8288F	APO-Salbutamol Inhaler, TX – SALBUTAMOL , salbutamol 100 microgram/actuation inhalation: pressurised, 200 actuations

Deletion – Equivalence Indicator

2390T	Austrapen, AL – AMPICILLIN , ampicillin 500 mg injection, 5 vials
3313J	Austrapen, AL – AMPICILLIN , ampicillin 500 mg injection, 5 vials (Dental)
1524F	Flubiclox, JU – FLUCLOXACILLIN , flucloxacillin 500 mg injection, 5 vials
5094D	Flubiclox, JU – FLUCLOXACILLIN , flucloxacillin 500 mg injection, 5 vials (Dental)

Alterations

Alteration – Authorised Prescriber

		From	To
10509D	TIOTROPIUM , tiotropium 2.5 microgram/actuation inhalation: solution, 60 actuations (<i>Spiriva Respimat</i>)	MP	MP,NP

Alteration – Restriction

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

10036F	ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID WITH CARBOHYDRATE , 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 (<i>keyomega</i>)
5502N	CARBOMER-974 , carbomer-974 0.3% eye gel, 30 x 500 mg unit doses (<i>Poly Gel</i>)(Optometrical)
8514D	CARBOMER-974 , carbomer-974 0.3% eye gel, 30 x 500 mg unit doses (<i>Poly Gel</i>)
5503P	CARBOMER-980 , carbomer-980 0.2% eye gel, 10 g (<i>Optifresh eye gel, PAA, Viscotears</i>)(Optometrical)

5504Q	CARBOMER-980 , carbomer-980 0.2% eye drops, 30 x 0.6 mL unit doses (<i>Viscotears Gel PF</i>)(Optometrical)
8384G	CARBOMER-980 , carbomer-980 0.2% eye gel, 10 g (<i>Optifresh eye gel, PAA, Viscotears</i>)
8578L	CARBOMER-980 , carbomer-980 0.2% eye drops, 30 x 0.6 mL unit doses (<i>Viscotears Gel PF</i>)
9210R	CARBOMER-980 , carbomer-980 0.2% eye gel, 10 g (<i>Optifresh eye gel, PAA, Viscotears</i>)
2324H	CARMELLOSE SODIUM , carmellose sodium 1% (4 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses (<i>Celluvisc, Optifresh Plus</i>)
2338C	CARMELLOSE SODIUM , carmellose sodium 0.5% (2 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses (<i>Cellufresh, Optifresh Tears</i>)
5505R	CARMELLOSE SODIUM , carmellose sodium 1% (4 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses (<i>Celluvisc, Optifresh Plus</i>)(Optometrical)
5506T	CARMELLOSE SODIUM , carmellose sodium 0.5% (2 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses (<i>Cellufresh, Optifresh Tears</i>)(Optometrical)
5509Y	CARMELLOSE SODIUM , carmellose sodium 0.25% (1.5 mg/0.6 mL) eye drops, 24 x 0.6 mL unit doses (<i>TheraTears</i>)(Optometrical)
5510B	CARMELLOSE SODIUM , carmellose sodium 1% (6 mg/0.6 mL) eye gel, 28 x 0.6 mL unit doses (<i>TheraTears</i>)(Optometrical)
8823J	CARMELLOSE SODIUM , carmellose sodium 0.25% (1.5 mg/0.6 mL) eye drops, 24 x 0.6 mL unit doses (<i>TheraTears</i>)
8824K	CARMELLOSE SODIUM , carmellose sodium 1% (6 mg/0.6 mL) eye gel, 28 x 0.6 mL unit doses (<i>TheraTears</i>)
5521N	DEXTRAN-70 + HYPROMELLOSE , dextran-70 0.1% + hypromellose 0.3% eye drops, 28 x 0.4 mL unit doses (<i>Bion Tears</i>)(Optometrical)
8299T	DEXTRAN-70 + HYPROMELLOSE , dextran-70 0.1% + hypromellose 0.3% eye drops, 28 x 0.4 mL unit doses (<i>Bion Tears</i>)
10040K	DOCOSAHEXAENOIC ACID WITH CARBOHYDRATE , docosahexaenoic acid with carbohydrate containing 200 mg docosahexaenoic acid oral liquid: powder for, 30 x 4g sachets (<i>docomega</i>)
5468T	DUTASTERIDE , dutasteride 500 microgram capsule, 30 (<i>Avodart</i>)
5490Y	DUTASTERIDE + TAMSULOSIN , dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram capsule: modified release, 30 (<i>Duodart 500ug/400ug</i>)
9113P	IMATINIB , imatinib 100 mg tablet, 60 (<i>Glivec</i>)
9114Q	IMATINIB , imatinib 400 mg tablet, 30 (<i>Glivec</i>)
3092R	MILK POWDER SYNTHETIC LOW CALCIUM , milk powder synthetic low calcium oral liquid: powder for, 400 g (<i>Locasol</i>)
1166J	PHENOXYBENZAMINE , phenoxybenzamine hydrochloride 10 mg capsule, 30 (<i>Amdipharm Mercury (Australia) Pty Limited</i>)
1862B	PHENOXYBENZAMINE , phenoxybenzamine hydrochloride 10 mg capsule, 100 (<i>Dibenziline</i>)
9286R	PHENOXYBENZAMINE , phenoxybenzamine hydrochloride 10 mg capsule, 100 (<i>Dibenziline</i>)
5532E	POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL , polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses (<i>Systane</i>)(Optometrical)
9170P	POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL , polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses (<i>Systane</i>)
2676W	PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES , protein hydrolysate formula with medium chain triglycerides oral liquid: powder for, 400 g (<i>Alfaré</i>)
8259Q	PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES , protein hydrolysate formula with medium chain triglycerides oral liquid: powder for, 450 g (<i>Aptamil Gold+ Pepti-Junior</i>)
1937Y	RANITIDINE , ranitidine 150 mg tablet: effervescent, 30 (<i>Zantac</i>)
1978D	RANITIDINE , ranitidine 150 mg tablet, 60 (<i>APO-Ranitidine, Ausran, Chem mart Ranitidine, GenRx Ranitidine, Rani 2, Ranitidine AN, Ranitidine GH, Ranitidine Sandoz, Ranoxyl, Terry White Chemists Ranitidine, Ulcaid, Zantac</i>)
10719E	RITUXIMAB , rituximab 1.4 g/11.7 mL injection, 11.7 mL vial (<i>Mabthera SC</i>)
10742J	RITUXIMAB , rituximab 1.4 g/11.7 mL injection, 11.7 mL vial (<i>Mabthera SC</i>)
2171G	SODIUM HYALURONATE , sodium hyaluronate 0.2% (2 mg/mL) eye drops, 10 mL (<i>Hylo-Forte</i>)(Optometrical)
2184Y	SODIUM HYALURONATE , sodium hyaluronate 0.1% (1 mg/mL) eye drops, 10 mL (<i>Hylo-Fresh</i>)(Optometrical)

5545W	SOY LECITHIN + TOCOPHEROLS + VITAMIN A , soy lecithin 1% + tocopherols 0.002% + vitamin A palmitate 0.025% eye spray, 100 actuations (<i>tearsagain</i>)(Optometrical)
9448G	SOY LECITHIN + TOCOPHEROLS + VITAMIN A , soy lecithin 1% + tocopherols 0.002% + vitamin A palmitate 0.025% eye spray, 100 actuations (<i>tearsagain</i>)
10049X	TRIGLYCERIDES MEDIUM CHAIN , triglycerides medium chain oral liquid, 18 x 250 mL cartons (<i>betaquik</i>)
3128P	TRIGLYCERIDES MEDIUM CHAIN , triglycerides medium chain oil: oral, 500 mL (<i>MCT Oil</i>)
9327X	TRIGLYCERIDES MEDIUM CHAIN , triglycerides medium chain oral liquid, 250 mL bottle (<i>Liquigen</i>)
9383W	TRIGLYCERIDES MEDIUM CHAIN FORMULA , triglycerides medium chain formula oral liquid: powder for, 30 x 16 g sachets (<i>MCT Pro-Cal</i>)
10149E	VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE , vitamins, minerals and trace elements with carbohydrate oral liquid: powder for, 30 x 6 g sachets (<i>FruitiVits</i>)
9328Y	VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE , vitamins, minerals and trace elements with carbohydrate oral liquid: powder for, 200 g (<i>Paediatric Seravit</i>)
2870C	WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, LONG CHAIN POLYUNSATURATED FATTY ACIDS, VITAMINS AND MINERALS, LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE , 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 (<i>Renastart</i>)
9382T	WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, LONG CHAIN POLYUNSATURATED FATTY ACIDS, VITAMINS AND MINERALS, LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE , 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 (<i>RenaStart</i>)
8587Y	WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, VITAMINS AND MINERALS, AND LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE , whey protein formula supplemented with amino acids, vitamins and minerals, and low in protein, phosphate, potassium and lactose oral liquid: powder for, 400 g (<i>Kindergen</i>)

Alteration – Restriction Level

		From	To
10036F	ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID WITH CARBOHYDRATE , 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 (<i>keyomega</i>)	authority-required	restricted
5502N	CARBOMER-974 , carbomer-974 0.3% eye gel, 30 x 500 mg unit doses (<i>Poly Gel</i>) (Optometrical)	authority-required	streamlined
5504Q	CARBOMER-980 , carbomer-980 0.2% eye drops, 30 x 0.6 mL unit doses (<i>Viscotears Gel PF</i>) (Optometrical)	authority-required	streamlined
5505R	CARMELLOSE SODIUM , carmellose sodium 1% (4 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses (<i>Celluvisc, Optifresh Plus</i>) (Optometrical)	authority-required	streamlined
5506T	CARMELLOSE SODIUM , carmellose sodium 0.5% (2 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses (<i>Cellufresh, Optifresh Tears</i>) (Optometrical)	authority-required	streamlined
5509Y	CARMELLOSE SODIUM , carmellose sodium 0.25% (1.5 mg/0.6 mL) eye drops, 24 x 0.6 mL unit doses (<i>TheraTears</i>) (Optometrical)	authority-required	streamlined
5510B	CARMELLOSE SODIUM , carmellose sodium 1% (6 mg/0.6 mL) eye gel, 28 x 0.6 mL unit doses (<i>TheraTears</i>) (Optometrical)	authority-required	streamlined
5521N	DEXTRAN-70 + HYPROMELLOSE , dextran-70 0.1% + hypromellose 0.3% eye drops, 28 x 0.4 mL unit doses (<i>Bion Tears</i>) (Optometrical)	authority-required	streamlined
10040K	DOCOSAHEXAENOIC ACID WITH CARBOHYDRATE , docosahexaenoic acid with carbohydrate containing 200 mg docosahexaenoic acid oral liquid: powder for, 30 x 4g sachets (<i>docomega</i>)	authority-required	restricted
3092R	MILK POWDER SYNTHETIC LOW CALCIUM , milk powder synthetic low calcium oral liquid: powder for, 400 g (<i>Locasol</i>)	authority-required	restricted
1166J	PHENOXYBENZAMINE , phenoxybenzamine hydrochloride 10 mg capsule, 30 (<i>Amdipharm Mercury (Australia) Pty Limited</i>)	authority-required	restricted
1862B	PHENOXYBENZAMINE , phenoxybenzamine hydrochloride 10 mg capsule, 100 (<i>Dibenyline</i>)	authority-required	restricted

9286R	PHENOXYBENZAMINE , phenoxybenzamine hydrochloride 10 mg capsule, 100 (<i>Dibenzyline</i>)	authority-required	restricted
5532E	POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL , polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses (<i>Systane</i>) (Optometrical)	authority-required	streamlined
2676W	PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES , protein hydrolysate formula with medium chain triglycerides oral liquid: powder for, 400 g (<i>Alfaré</i>)	authority-required	streamlined
8259Q	PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES , protein hydrolysate formula with medium chain triglycerides oral liquid: powder for, 450 g (<i>Aptamil Gold+ Pepti-Junior</i>)	authority-required	streamlined
2171G	SODIUM HYALURONATE , sodium hyaluronate 0.2% (2 mg/mL) eye drops, 10 mL (<i>Hylo-Forte</i>) (Optometrical)	authority-required	streamlined
2184Y	SODIUM HYALURONATE , sodium hyaluronate 0.1% (1 mg/mL) eye drops, 10 mL (<i>Hylo-Fresh</i>) (Optometrical)	authority-required	streamlined
5545W	SOY LECITHIN + TOCOPHEROLS + VITAMIN A , soy lecithin 1% + tocopherols 0.002% + vitamin A palmitate 0.025% eye spray, 100 actuations (<i>tearsagain</i>) (Optometrical)	authority-required	streamlined
10049X	TRIGLYCERIDES MEDIUM CHAIN , triglycerides medium chain oral liquid, 18 x 250 mL cartons (<i>betaquik</i>)	authority-required	streamlined
3128P	TRIGLYCERIDES MEDIUM CHAIN , triglycerides medium chain oil: oral, 500 mL (<i>MCT Oil</i>)	authority-required	streamlined
9327X	TRIGLYCERIDES MEDIUM CHAIN , triglycerides medium chain oral liquid, 250 mL bottle (<i>Liquigen</i>)	authority-required	streamlined
9383W	TRIGLYCERIDES MEDIUM CHAIN FORMULA , triglycerides medium chain formula oral liquid: powder for, 30 x 16 g sachets (<i>MCT Pro-Cal</i>)	authority-required	streamlined
10149E	VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE , vitamins, minerals and trace elements with carbohydrate oral liquid: powder for, 30 x 6 g sachets (<i>FruitiVits</i>)	authority-required	restricted
9328Y	VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE , vitamins, minerals and trace elements with carbohydrate oral liquid: powder for, 200 g (<i>Paediatric Seravit</i>)	authority-required	restricted
2870C	WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, LONG CHAIN POLYUNSATURATED FATTY ACIDS, VITAMINS AND MINERALS, LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE , 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 (<i>Renastart</i>)	authority-required	streamlined
9382T	WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, LONG CHAIN POLYUNSATURATED FATTY ACIDS, VITAMINS AND MINERALS, LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE , 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 (<i>RenaStart</i>)	authority-required	streamlined
8587Y	WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, VITAMINS AND MINERALS, AND LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE , whey protein formula supplemented with amino acids, vitamins and minerals, and low in protein, phosphate, potassium and lactose oral liquid: powder for, 400 g (<i>Kindergen</i>)	authority-required	streamlined

Alteration – Manufacturer Code

		From	To
8361C	<i>Capecitabine MYX</i> – CAPECITABINE , capecitabine 150 mg tablet, 60	YN	OC
8362D	<i>Capecitabine MYX</i> – CAPECITABINE , capecitabine 500 mg tablet, 120	YN	OC
2479L	<i>Aridon APN 10</i> – DONEPEZIL , donepezil hydrochloride 10 mg tablet, 28	FM	RF
8496E	<i>Aridon APN 10</i> – DONEPEZIL , donepezil hydrochloride 10 mg tablet, 28	FM	RF
2532G	<i>Aridon APN 5</i> – DONEPEZIL , donepezil hydrochloride 5 mg tablet, 28	FM	RF

8495D	<i>Aridon APN 5</i> – DONEPEZIL , donepezil hydrochloride 5 mg tablet, 28	FM	RF
8600P	<i>Nexole</i> – ESOMEPRAZOLE , esomeprazole 20 mg tablet: enteric, 30	QA	RF
8886Q	<i>Nexole</i> – ESOMEPRAZOLE , esomeprazole 20 mg tablet: enteric, 30	QA	RF
3401B	<i>Nexole</i> – ESOMEPRAZOLE , esomeprazole 40 mg tablet: enteric, 30	QA	RF
8601Q	<i>Nexole</i> – ESOMEPRAZOLE , esomeprazole 40 mg tablet: enteric, 30	QA	RF
5043K	<i>Accu-Chek Aviva</i> – GLUCOSE INDICATOR BLOOD , glucose indicator blood diagnostic strip, 50	RD	RP
5053Y	<i>Accu-Chek Aviva</i> – GLUCOSE INDICATOR BLOOD , glucose indicator blood diagnostic strip, 50	RD	RP
8739Y	<i>Accu-Chek Go</i> – GLUCOSE INDICATOR BLOOD , glucose indicator blood diagnostic strip, 50	RD	RP
9274D	<i>Accu-Chek Go</i> – GLUCOSE INDICATOR BLOOD , glucose indicator blood diagnostic strip, 50	RD	RP
2979T	<i>Accu-Chek Performa</i> – GLUCOSE INDICATOR BLOOD , glucose indicator blood diagnostic strip, 100	RD	RP
8190C	<i>Accu-Chek Active</i> – GLUCOSE INDICATOR BLOOD , glucose indicator blood diagnostic strip, 100	RD	RP
9257F	<i>Accu-Chek Performa</i> – GLUCOSE INDICATOR BLOOD , glucose indicator blood diagnostic strip, 100	RD	RP
9273C	<i>Accu-Chek Active</i> – GLUCOSE INDICATOR BLOOD , glucose indicator blood diagnostic strip, 100	RD	RP
9300L	<i>Accu-Chek Mobile</i> – GLUCOSE INDICATOR BLOOD , glucose indicator blood diagnostic strip, 100	RD	RP
9301M	<i>Accu-Chek Mobile</i> – GLUCOSE INDICATOR BLOOD , glucose indicator blood diagnostic strip, 100	RD	RP
2588F	<i>Isordil Sublingual</i> – ISOSORBIDE DINITRATE , isosorbide dinitrate 5 mg tablet: sublingual, 100	QA	RW
1818Q	<i>Methotrexate MYX</i> – METHOTREXATE , METHOTREXATE Injection 50 mg in 2 mL, 1	YN	OC
5232J	<i>Zydol</i> – TRAMADOL , tramadol hydrochloride 50 mg capsule, 20 (Dental)	QA	RW
8455B	<i>Zydol</i> – TRAMADOL , tramadol hydrochloride 50 mg capsule, 20	QA	RW
8611F	<i>Zydol</i> – TRAMADOL , tramadol hydrochloride 50 mg capsule, 20	QA	RW
8523N	<i>Zydol SR 100</i> – TRAMADOL , tramadol hydrochloride 100 mg tablet: modified release, 20	QA	RW
8524P	<i>Zydol SR 150</i> – TRAMADOL , tramadol hydrochloride 150 mg tablet: modified release, 20	QA	RW
8525Q	<i>Zydol SR 200</i> – TRAMADOL , tramadol hydrochloride 200 mg tablet: modified release, 20	QA	RW

Advance Notices

1 July 2016

Deletion – Brand

9049G	<i>Cadatin 5/10, FZ</i> – AMLODIPINE + ATORVASTATIN , amlodipine 5 mg + atorvastatin 10 mg tablet, 30
9050H	<i>Cadatin 5/20, FZ</i> – AMLODIPINE + ATORVASTATIN , amlodipine 5 mg + atorvastatin 20 mg tablet, 30
9051J	<i>Cadatin 5/40, FZ</i> – AMLODIPINE + ATORVASTATIN , amlodipine 5 mg + atorvastatin 40 mg tablet, 30
9052K	<i>Cadatin 5/80, FZ</i> – AMLODIPINE + ATORVASTATIN , amlodipine 5 mg + atorvastatin 80 mg tablet, 30
9053L	<i>Cadatin 10/10, FZ</i> – AMLODIPINE + ATORVASTATIN , amlodipine 10 mg + atorvastatin 10 mg tablet, 30
9054M	<i>Cadatin 10/20, FZ</i> – AMLODIPINE + ATORVASTATIN , amlodipine 10 mg + atorvastatin 20 mg tablet, 30
9055N	<i>Cadatin 10/40, FZ</i> – AMLODIPINE + ATORVASTATIN , amlodipine 10 mg + atorvastatin 40 mg tablet, 30
9056P	<i>Cadatin 10/80, FZ</i> – AMLODIPINE + ATORVASTATIN , amlodipine 10 mg + atorvastatin 80 mg tablet, 30
1884E	<i>Amoxycillin-GA, FM</i> – AMOXYCILLIN , amoxycillin 250 mg capsule, 20

1889K	<i>Amoxicillin-GA, FM</i> – AMOXYCILLIN , amoxicillin 500 mg capsule, 20
3300Q	<i>Amoxicillin-GA, FM</i> – AMOXYCILLIN , amoxicillin 500 mg capsule, 20 (Dental)
3301R	<i>Amoxicillin-GA, FM</i> – AMOXYCILLIN , amoxicillin 250 mg capsule, 20 (Dental)
1891M	<i>GA-Amclav 500/125, FM</i> – AMOXYCILLIN + CLAVULANIC ACID , amoxicillin 500 mg + clavulanic acid 125 mg tablet, 10
1892N	<i>GA-Amclav 125/31.25, FM</i> – AMOXYCILLIN + CLAVULANIC ACID , amoxicillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL oral liquid: powder for, 75 mL
5006L	<i>GA-Amclav Forte 875/125, FM</i> – AMOXYCILLIN + CLAVULANIC ACID , amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10 (Dental)
5008N	<i>GA-Amclav 500/125, FM</i> – AMOXYCILLIN + CLAVULANIC ACID , amoxicillin 500 mg + clavulanic acid 125 mg tablet, 10 (Dental)
5009P	<i>GA-Amclav 125/31.25, FM</i> – AMOXYCILLIN + CLAVULANIC ACID , amoxicillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL oral liquid: powder for, 75 mL (Dental)
5011R	<i>GA-Amclav Forte 400/57, FM</i> – AMOXYCILLIN + CLAVULANIC ACID , amoxicillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL oral liquid: powder for, 60 mL (Dental)
8254K	<i>GA-Amclav Forte 875/125, FM</i> – AMOXYCILLIN + CLAVULANIC ACID , amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10
8319W	<i>GA-Amclav Forte 400/57, FM</i> – AMOXYCILLIN + CLAVULANIC ACID , amoxicillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL oral liquid: powder for, 60 mL
1473M	<i>Fluconazole Hexal, HX</i> – FLUCONAZOLE , fluconazole 100 mg/50 mL injection, 50 mL vial
1474N	<i>Fluconazole Hexal, HX</i> – FLUCONAZOLE , fluconazole 200 mg/100 mL injection, 100 mL vial

1 August 2016

Deletion – Brand

3036T *Protos 2 g, SE* – **STRONTIUM**, strontium ranelate 2 g granules, 28 x 2 g sachets

Delisting of strontium will be recommended for determination to take effect 1 August 2016 in accordance with Pharmaceutical Benefits Advisory Committee advice to the Minister. There are alternative therapies available.

1 September 2016

Deletion – Brand

8423H *Dilaudid-HP, MF* – **HYDROMORPHONE**, hydromorphone hydrochloride 500 mg/50 mL injection, 50 mL vial

Palliative Care

Deletions

Deletion – Item

5386L	BENZYDAMINE , benzydamine hydrochloride 0.15% mouthwash, 500 mL (<i>Difflam</i>)
5307H	BISACODYL , bisacodyl 10 mg suppository, 10 (<i>Dulcolax, Petrus Bisacodyl Suppositories</i>)
5308J	BISACODYL , bisacodyl 10 mg suppository, 12 (<i>Petrus Bisacodyl Suppositories</i>)
5306G	BISACODYL , bisacodyl 10 mg/5 mL enema, 25 x 5 mL (<i>Bisalax</i>)
5305F	BISACODYL , bisacodyl 5 mg tablet: enteric, 200 (<i>Lax-Tab</i>)
5342E	CLONAZEPAM , clonazepam 2.5 mg/mL oral liquid, 10 mL (<i>Rivotril</i>)
5340C	CLONAZEPAM , clonazepam 500 microgram tablet, 100 (<i>Paxam 0.5, Rivotril</i>)
5341D	CLONAZEPAM , clonazepam 2 mg tablet, 100 (<i>Paxam 2, Rivotril</i>)
5357Y	DIAZEPAM , diazepam 2 mg tablet, 50 (<i>APO-Diazepam, Antenex 2, Ranzepam, Valpam 2</i>)
5358B	DIAZEPAM , diazepam 5 mg tablet, 50 (<i>APO-Diazepam, Antenex 5, Ranzepam, Valium, Valpam 5</i>)

5366K	DICLOFENAC , diclofenac sodium 100 mg suppository, 20 (<i>Voltaren 100</i>)
5364H	DICLOFENAC , diclofenac sodium 25 mg tablet: enteric, 50 (<i>APO-Diclofenac, Chem mart Diclofenac, Clonac 25, Diclofenac AN, Diclofenac Sandoz, Diclofenac-GA, Fenac 25, Terry White Chemists Diclofenac, Voltaren 25</i>)
5365J	DICLOFENAC , diclofenac sodium 50 mg tablet: enteric, 50 (<i>APO-Diclofenac, Chem mart Diclofenac, Clonac 50, Diclofenac AN, Diclofenac Sandoz, Diclofenac-GA, Fenac, Terry White Chemists Diclofenac, Voltaren 50</i>)
5318X	HYOSCINE BUTYLBROMIDE , hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules (<i>Buscopan</i>)
5370P	IBUPROFEN , ibuprofen 400 mg tablet, 30 (<i>Brufen</i>)
5379D	INDOMETHACIN , indomethacin 25 mg capsule, 50 (<i>Arthrexin, Indocid</i>)
5380E	INDOMETHACIN , indomethacin 100 mg suppository, 20 (<i>Indocid</i>)
5427P	MACROGOL-3350 , macrogol-3350 1 g/g oral liquid: powder for, 510 g (<i>OsmoLax</i>)
2353W	MACROGOL-3350 , macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets (<i>Herron ClearLax</i>)
10112F	MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDE , 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 (<i>Movicol Liquid</i>)
5390Q	MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDE , 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 (<i>APO-MACROGOL plus ELECTROLYTES, Chemists' Own Macrogol with Electrolytes, LaxaCon, Macrovic, Molaxole, Movicol, lax-sachets</i>)
5395Y	MORPHINE , morphine sulfate 10 mg tablet, 20 (<i>Sevredol</i>)
5396B	MORPHINE , morphine sulfate 20 mg tablet, 20 (<i>Sevredol</i>)
5392T	MORPHINE , morphine sulfate 200 mg tablet: modified release, 28 (<i>MS Contin</i>)
5398D	NAPROXEN , naproxen 125 mg/5 mL oral liquid, 474 mL (<i>Phebra Naproxen Suspension</i>)
5349M	NAPROXEN , naproxen 250 mg tablet, 50 (<i>Inza 250, Naprosyn</i>)
5350N	NAPROXEN , naproxen 500 mg tablet, 50 (<i>Inza 500, Naprosyn</i>)
5354T	NAPROXEN , naproxen sodium 550 mg tablet, 50 (<i>Anaprox 550, Crysanal</i>)
5351P	NAPROXEN , naproxen 750 mg tablet: modified release, 28 (<i>Naprosyn SR750, Proxen SR 750</i>)
5352Q	NAPROXEN , naproxen 1 g tablet: modified release, 28 (<i>Naprosyn SR1000, Proxen SR 1000</i>)
5360D	NITRAZEPAM , nitrazepam 5 mg tablet, 25 (<i>Alodorm, Mogadon</i>)
5373T	OXAZEPAM , oxazepam 15 mg tablet, 25 (<i>Alepam 15, Serepax</i>)
5374W	OXAZEPAM , oxazepam 30 mg tablet, 25 (<i>APO-Oxazepam, Alepam 30, Murelax, Serepax</i>)
5320B	PARACETAMOL , paracetamol 500 mg suppository, 24 (<i>Panadol</i>)
5344G	PARACETAMOL , paracetamol 665 mg tablet: modified release, 96 (<i>Osteomol 665 Paracetamol</i>)
5324F	RHAMNUS FRANGULA + STERCULIA , rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g (<i>Normacol Plus</i>)
5332P	SORBITOL + CITRIC ACID + LAURYL SULFOACETATE SODIUM , 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 (<i>Micolette, Microlax</i>)
5376Y	TEMAZEPAM , temazepam 10 mg tablet, 25 (<i>APO-Temazepam, Normison, Temaze, Temtabs</i>)

Alterations

Alteration – Restriction

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

5385K	BENZYDAMINE , benzydamine hydrochloride 0.15% mouthwash, 500 mL (<i>Difflam</i>)
5301B	BISACODYL , bisacodyl 5 mg tablet: enteric, 200 (<i>Lax-Tab</i>)
5302C	BISACODYL , bisacodyl 10 mg/5 mL enema, 25 x 5 mL (<i>Bisalax</i>)
5303D	BISACODYL , bisacodyl 10 mg suppository, 10 (<i>Dulcolax, Petrus Bisacodyl Suppositories</i>)
5304E	BISACODYL , bisacodyl 10 mg suppository, 12 (<i>Petrus Bisacodyl Suppositories</i>)
5337X	CLONAZEPAM , clonazepam 500 microgram tablet, 100 (<i>Paxam 0.5, Rivotril</i>)
5338Y	CLONAZEPAM , clonazepam 2 mg tablet, 100 (<i>Paxam 2, Rivotril</i>)

5339B	CLONAZEPAM , clonazepam 2.5 mg/mL oral liquid, 10 mL (<i>Rivotril</i>)
5355W	DIAZEPAM , diazepam 2 mg tablet, 50 (<i>APO-Diazepam, Antenex 2, Ranzepam, Valpam 2</i>)
5356X	DIAZEPAM , diazepam 5 mg tablet, 50 (<i>APO-Diazepam, Antenex 5, Ranzepam, Valium, Valpam 5</i>)
5361E	DICLOFENAC , diclofenac sodium 25 mg tablet: enteric, 50 (<i>APO-Diclofenac, Chem mart Diclofenac, Clonac 25, Diclofenac AN, Diclofenac Sandoz, Diclofenac-GA, Fenac 25, Terry White Chemists Diclofenac, Voltaren 25</i>)
5362F	DICLOFENAC , diclofenac sodium 50 mg tablet: enteric, 50 (<i>APO-Diclofenac, Chem mart Diclofenac, Clonac 50, Diclofenac AN, Diclofenac Sandoz, Diclofenac-GA, Fenac, Terry White Chemists Diclofenac, Voltaren 50</i>)
5363G	DICLOFENAC , diclofenac sodium 100 mg suppository, 20 (<i>Voltaren 100</i>)
5317W	HYOSCINE BUTYLBROMIDE , hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules (<i>Buscopan</i>)
5368M	IBUPROFEN , ibuprofen 400 mg tablet, 30 (<i>Brufen</i>)
5377B	INDOMETHACIN , indomethacin 25 mg capsule, 50 (<i>Arthrexin, Indocid</i>)
5378C	INDOMETHACIN , indomethacin 100 mg suppository, 20 (<i>Indocid</i>)
2351R	MACROGOL-3350 , macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets (<i>Herron ClearLax</i>)
5426N	MACROGOL-3350 , macrogol-3350 1 g/g oral liquid: powder for, 510 g (<i>OsmoLax</i>)
10127B	MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDE , 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 (<i>Movicol Liquid</i>)
5389P	MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDE , 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 (<i>APO-MACROGOL plus ELECTROLYTES, Chemists' Own Macrogol with Electrolytes, LaxaCon, Macrovic, Molaxole, Movicol, lax-sachets</i>)
5423K	METHYLNALTREXONE , methylnaltrexone bromide 12 mg/0.6 mL injection, 0.6 mL vial (<i>Relistor</i>)
5424L	METHYLNALTREXONE , METHYLNALTREXONE Solution for injection containing methylnaltrexone bromide 12 mg in 0.6 mL, 7 (<i>Relistor</i>)
5391R	MORPHINE , morphine sulfate 200 mg tablet: modified release, 28 (<i>MS Contin</i>)
5393W	MORPHINE , morphine sulfate 10 mg tablet, 20 (<i>Sevredol</i>)
5394X	MORPHINE , morphine sulfate 20 mg tablet, 20 (<i>Sevredol</i>)
5345H	NAPROXEN , naproxen 250 mg tablet, 50 (<i>Inza 250, Naprosyn</i>)
5346J	NAPROXEN , naproxen 500 mg tablet, 50 (<i>Inza 500, Naprosyn</i>)
5347K	NAPROXEN , naproxen 750 mg tablet: modified release, 28 (<i>Naprosyn SR750, Proxen SR 750</i>)
5348L	NAPROXEN , naproxen 1 g tablet: modified release, 28 (<i>Naprosyn SR1000, Proxen SR 1000</i>)
5353R	NAPROXEN , naproxen sodium 550 mg tablet, 50 (<i>Anaprox 550, Crysanal</i>)
5397C	NAPROXEN , naproxen 125 mg/5 mL oral liquid, 474 mL (<i>Phebra Naproxen Suspension</i>)
5359C	NITRAZEPAM , nitrazepam 5 mg tablet, 25 (<i>Alodorm, Mogadon</i>)
5371Q	OXAZEPAM , oxazepam 15 mg tablet, 25 (<i>Alepam 15, Serepax</i>)
5372R	OXAZEPAM , oxazepam 30 mg tablet, 25 (<i>APO-Oxazepam, Alepam 30, Murelax, Serepax</i>)
5319Y	PARACETAMOL , paracetamol 500 mg suppository, 24 (<i>Panadol</i>)
5343F	PARACETAMOL , paracetamol 665 mg tablet: modified release, 96 (<i>Osteomol 665 Paracetamol</i>)
5322D	RHAMNUS FRANGULA + STERCULIA , rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g (<i>Normacol Plus</i>)
5331N	SORBITOL + CITRIC ACID + LAURYL SULFOACETATE SODIUM , 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 (<i>Micolette, Microlax</i>)
5375X	TEMAZEPAM , temazepam 10 mg tablet, 25 (<i>APO-Temazepam, Normison, Temaze, Temtabs</i>)

Alteration – Restriction Level

		<i>From</i>	<i>To</i>
5301B	BISACODYL , bisacodyl 5 mg tablet: enteric, 200 (<i>Lax-Tab</i>)	streamlined	restricted
5302C	BISACODYL , bisacodyl 10 mg/5 mL enema, 25 x 5 mL (<i>Bisalax</i>)	streamlined	restricted

5303D	BISACODYL , bisacodyl 10 mg suppository, 10 (<i>Dulcolax, Petrus Bisacodyl Suppositories</i>)	streamlined	restricted
5304E	BISACODYL , bisacodyl 10 mg suppository, 12 (<i>Petrus Bisacodyl Suppositories</i>)	streamlined	restricted
5361E	DICLOFENAC , diclofenac sodium 25 mg tablet: enteric, 50 (<i>APO-Diclofenac, Chem mart Diclofenac, Clonac 25, Diclofenac AN, Diclofenac Sandoz, Diclofenac-GA, Fenac 25, Terry White Chemists Diclofenac, Voltaren 25</i>)	streamlined	restricted
5362F	DICLOFENAC , diclofenac sodium 50 mg tablet: enteric, 50 (<i>APO-Diclofenac, Chem mart Diclofenac, Clonac 50, Diclofenac AN, Diclofenac Sandoz, Diclofenac-GA, Fenac, Terry White Chemists Diclofenac, Voltaren 50</i>)	streamlined	restricted
5363G	DICLOFENAC , diclofenac sodium 100 mg suppository, 20 (<i>Voltaren 100</i>)	authority-required	restricted
5368M	IBUPROFEN , ibuprofen 400 mg tablet, 30 (<i>Brufen</i>)	authority-required	restricted
5377B	INDOMETHACIN , indomethacin 25 mg capsule, 50 (<i>Arthrexin, Indocid</i>)	streamlined	restricted
5378C	INDOMETHACIN , indomethacin 100 mg suppository, 20 (<i>Indocid</i>)	authority-required	restricted
5423K	METHYLNALTREXONE , methylnaltrexone bromide 12 mg/0.6 mL injection, 0.6 mL vial (<i>Relistor</i>)	authority-required	streamlined
5424L	METHYLNALTREXONE , METHYLNALTREXONE Solution for injection containing methylnaltrexone bromide 12 mg in 0.6 mL, 7 (<i>Relistor</i>)	authority-required	streamlined
5345H	NAPROXEN , naproxen 250 mg tablet, 50 (<i>Inza 250, Naprosyn</i>)	streamlined	restricted
5346J	NAPROXEN , naproxen 500 mg tablet, 50 (<i>Inza 500, Naprosyn</i>)	streamlined	restricted
5347K	NAPROXEN , naproxen 750 mg tablet: modified release, 28 (<i>Naprosyn SR750, Proxen SR 750</i>)	streamlined	restricted
5348L	NAPROXEN , naproxen 1 g tablet: modified release, 28 (<i>Naprosyn SR1000, Proxen SR 1000</i>)	streamlined	restricted
5353R	NAPROXEN , naproxen sodium 550 mg tablet, 50 (<i>Anaprox 550, Crysanal</i>)	streamlined	restricted
5397C	NAPROXEN , naproxen 125 mg/5 mL oral liquid, 474 mL (<i>Phebra Naproxen Suspension</i>)	streamlined	restricted
5319Y	PARACETAMOL , paracetamol 500 mg suppository, 24 (<i>Panadol</i>)	streamlined	restricted
5343F	PARACETAMOL , paracetamol 665 mg tablet: modified release, 96 (<i>Osteomol 665 Paracetamol</i>)	streamlined	restricted
5322D	RHAMNUS FRANGULA + STERCULIA , rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g (<i>Normacol Plus</i>)	streamlined	restricted
5331N	SORBITOL + CITRIC ACID + LAURYL SULFOACETATE SODIUM , 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 (<i>Micolette, Microlax</i>)	streamlined	restricted

Alteration – Maximum Quantity

		From	To
5423K	METHYLNALTREXONE , methylnaltrexone bromide 12 mg/0.6 mL injection, 0.6 mL vial (<i>Relistor</i>)	3	7

Highly Specialised Drugs Program (Private Hospital)

Additions

Addition – Brand

6100C	<i>Azadine, RZ</i> – AZACITIDINE , azacitidine 100 mg injection, 1 vial
6138C	<i>Azadine, RZ</i> – AZACITIDINE , azacitidine 100 mg injection, 1 vial

Addition – Equivalence Indicator

- 6100C *Vidaza, CJ* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial
6138C *Vidaza, CJ* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

Alterations

Alteration – Restriction

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

- 6100C **AZACITIDINE**, azacitidine 100 mg injection, 1 vial (*Azadine, Vidaza*)
6138C **AZACITIDINE**, azacitidine 100 mg injection, 1 vial (*Azadine, Vidaza*)
9744W **LEVODOPA + CARBIDOPA ANHYDROUS**, levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL (*Duodopa*)
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*)

Highly Specialised Drugs Program (Public Hospital)

Additions

Addition – Brand

- 9597D *Azadine, RZ* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial
9598E *Azadine, RZ* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

Addition – Equivalence Indicator

- 9597D *Vidaza, CJ* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial
9598E *Vidaza, CJ* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

Alterations

Alteration – Restriction

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

- 9597D **AZACITIDINE**, azacitidine 100 mg injection, 1 vial (*Azadine, Vidaza*)
9598E **AZACITIDINE**, azacitidine 100 mg injection, 1 vial (*Azadine, Vidaza*)
9743T **LEVODOPA + CARBIDOPA ANHYDROUS**, levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL (*Duodopa*)
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*)

Highly Specialised Drugs Program (Community Access)

Advance Notices

1 August 2016

Deletion – Brand

- 10372X *Sebivo, NV* – **TELBIVUDINE**, telbivudine 600 mg tablet, 28

Repatriation Pharmaceutical Benefits Additions


Addition – Item

- 10586E **GLYCEROL**, glycerol 700 mg suppository, 12 (*Petrus Pharmaceuticals Pty Ltd*)
- 10596Q **GLYCEROL**, glycerol 1.4 g suppository, 12 (*Petrus Pharmaceuticals Pty Ltd*)
- 4246L **GLYCEROL**, glycerol 2.8 g suppository, 12 (*Petrus Pharmaceuticals Pty Ltd*)

Prescriber Bag

▪ NALOXONE

naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules

10786Q	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
 2	2	*180.41	Naloxone Hydrochloride (DBL) [HH]

General Pharmaceutical Benefits

▪ ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID WITH CARBOHYDRATE

Restricted benefit

Peroxisomal biogenesis disorders

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

10036F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*362.65	38.30	keyomega [VF]

▪ CARBOMER-974

Authority required (STREAMLINED)

6172

Severe dry eye syndrome

Clinical criteria:

Patient must be sensitive to preservatives in multi-dose eye drops.

carbomer-974 0.3% eye gel, 30 x 500 mg unit doses

5502N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	3	5	..	*34.89	36.06	Poly Gel [AQ]

carbomer-974 0.3% eye gel, 30 x 500 mg unit doses

8514D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	..	*34.89	36.06	Poly Gel [AQ]

▪ CARBOMER-980

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

carbomer-980 0.2% eye gel, 10 g

5503P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
OP	‡1	5	..	13.24	14.41	^a Optifresh eye gel [PP]	^a PAA [IQ]
			^B 3.85	17.09	14.41	^a Viscotears [AQ]	

carbomer-980 0.2% eye gel, 10 g

8384G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	‡1	5	..	13.24	14.41	^a Optifresh eye gel [PP]	^a PAA [IQ]
			^B 3.85	17.09	14.41	^a Viscotears [AQ]	

▪ CARBOMER-980

Authority required (STREAMLINED)

6172

Severe dry eye syndrome

Clinical criteria:

Patient must be sensitive to preservatives in multi-dose eye drops.

carbomer-980 0.2% eye drops, 30 x 0.6 mL unit doses

5504Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	3	5	..	*36.21	37.38	Viscotears Gel PF [AQ]

carbomer-980 0.2% eye drops, 30 x 0.6 mL unit doses

8578L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	..	*36.21	37.38	Viscotears Gel PF [AQ]

■ CARBOMER-980

Note No applications for increased maximum quantities will be authorised.

Note No applications for repeats will be authorised.

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

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.

carbomer-980 0.2% eye gel, 10 g

9210R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	‡1	11	..	13.24	14.41	^a Optifresh eye gel [PP]	^a PAA [IQ]
			^B 3.85	17.09	14.41	^a Viscotears [AQ]	

■ CARMELLOSE SODIUM

Authority required (STREAMLINED)

6172

Severe dry eye syndrome

Clinical criteria:

Patient must be sensitive to preservatives in multi-dose eye drops.

carmellose sodium 1% (4 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses

2324H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	3	5	..	*30.96	32.13	^a Optifresh Plus [PP]	
			^B 7.29	*38.25	32.13	^a Celluvisc [AG]	

carmellose sodium 1% (4 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses

5505R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
OP	3	5	..	*30.96	32.13	^a Optifresh Plus [PP]	
			^B 7.29	*38.25	32.13	^a Celluvisc [AG]	

carmellose sodium 0.25% (1.5 mg/0.6 mL) eye drops, 24 x 0.6 mL unit doses

5509Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
OP	4	5	..	*38.49	38.30	TheraTears [CX]	

carmellose sodium 0.25% (1.5 mg/0.6 mL) eye drops, 24 x 0.6 mL unit doses

8823J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	5	..	*38.49	38.30	TheraTears [CX]	

carmellose sodium 0.5% (2 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses

2338C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	3	5	..	*30.96	32.13	^a Optifresh Tears [PP]	
			^B 7.29	*38.25	32.13	^a Cellufresh [AG]	

carmellose sodium 0.5% (2 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses

5506T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
OP	3	5	..	*30.96	32.13	^a Optifresh Tears [PP]	
			^B 7.29	*38.25	32.13	^a Cellufresh [AG]	

carmellose sodium 1% (6 mg/0.6 mL) eye gel, 28 x 0.6 mL unit doses

5510B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
OP	3	5	..	*33.27	34.44	TheraTears [CX]	

carmellose sodium 1% (6 mg/0.6 mL) eye gel, 28 x 0.6 mL unit doses

8824K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	3	5	..	*33.27	34.44	TheraTears [CX]	

■ CEPHALEXIN

Authority required (STREAMLINED)

6188

Osteomyelitis

cephalexin 500 mg capsule, 20

10778G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	1	..	*13.57	14.74	^a APO-Cephalexin [TX]	^a Cefalexin Sandoz [SZ]
						^a Cephalex 500 [CR]	^a Cephalexin AN [EA]
						^a Cephalexin generichealth [GQ]	^a Chem mart Cephalexin [CH]

^a Cilex [ED]
^a Ibilex 500 [AF]
^a Terry White Chemists
 Cephalexin [TW]
^a Keflex [AS]

^B10.94 *24.51 14.74

▪ **DEXTRAN-70 + HYPROMELLOSE**

Authority required (STREAMLINED)

6172

Severe dry eye syndrome

Clinical criteria:

Patient must be sensitive to preservatives in multi-dose eye drops.

dextran-70 0.1% + hypromellose 0.3% eye drops, 28 x 0.4 mL unit doses

5521N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	3	5	..	*35.31	36.48	Bion Tears [AQ]

dextran-70 0.1% + hypromellose 0.3% eye drops, 28 x 0.4 mL unit doses

8299T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	..	*35.31	36.48	Bion Tears [AQ]

▪ **DICLOXACILLIN**

Authority required (STREAMLINED)

6188

Osteomyelitis

dicloxacillin 500 mg capsule, 24

10790X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*29.71	30.88	Distaph 500 [AF]

▪ **DOCOSAHEXAENOIC ACID WITH CARBOHYDRATE**

Restricted benefit

Peroxisomal biogenesis disorders

docosahexaenoic acid with carbohydrate containing 200 mg docosahexaenoic acid oral liquid: powder for, 30 x 4g sachets

10040K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*362.65	38.30	docomega [VF]

▪ **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.

Restricted benefit

Severe acne

doxycycline 100 mg capsule: modified release, 7

10777F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	^B 6.16	*20.37	15.38	^a Mayne Pharma Doxycycline [YT]
			^B 11.84	*26.05	15.38	^a Doryx [YN]

doxycycline 100 mg tablet, 7

10779H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*14.21	15.38	^a Doxsig [RW] ^a Doxycycline AN [EA]	^a Doxy-100 [ED] ^a Doxylin 100 [AF]

doxycycline 100 mg tablet, 7

10781K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*14.21	15.38	^a Chem mart Doxycycline [CH] ^a GenRx Doxycycline [GX]	^a Doxycycline Sandoz [HX] ^a Terry White Chemists Doxycycline [TW]

▪ **DUTASTERIDE**

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.

Authority required (STREAMLINED)

6202

Benign prostatic hyperplasia

Clinical criteria:

Patient must have lower urinary tract symptoms, AND

Patient must have moderate to severe benign prostatic hyperplasia, AND

The treatment must be in combination with an alpha-antagonist.

dutasteride 500 microgram capsule, 30

5468T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	30.26	31.43	Avodart [GK]

▪ DUTASTERIDE + TAMSULOSIN**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.

Authority required (STREAMLINED)**6189**

Benign prostatic hyperplasia

Clinical criteria:

Patient must have lower urinary tract symptoms, AND

Patient must have moderate to severe benign prostatic hyperplasia.

dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram capsule: modified release, 30

5490Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	34.47	35.64	Duodart 500ug/400ug [GK]

▪ ERYTHROMYCIN**Authority required (STREAMLINED)****6160**

Severe acne

Clinical criteria:

The condition must be one in which tetracycline therapy is inappropriate.

erythromycin 250 mg capsule: enteric, 25

10780J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*19.99	21.16	^a Mayne Pharma Erythromycin [YT]
			^b 5.06	*25.05	21.16	^a Eryc [YN]

▪ ERYTHROMYCIN ETHYLSUCCINATE**Authority required (STREAMLINED)****6160**

Severe acne

Clinical criteria:

The condition must be one in which tetracycline therapy is inappropriate.

erythromycin (as ethylsuccinate) 400 mg tablet, 25

10789W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*20.23	21.40	^a E-Mycin [AF]
			^b 4.66	*24.89	21.40	^a E.E.S. 400 Filmtab [ZC]

▪ FLUCLOXACILLIN**Caution** Severe cholestatic jaundice has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.**Authority required (STREAMLINED)****6169**

Osteomyelitis

flucloxacillin 500 mg capsule, 24

10788T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	1	..	*27.81	28.98	^a APO-Flucloxacillin [TX]	^a Flopen [AS]
						^a Staphylex 500 [AF]	

▪ FUSIDATE**Authority required (STREAMLINED)****6133**

Osteomyelitis

Clinical criteria:

The condition must be methicillin-resistant staphylococcal aureus (MRSA), AND
The treatment must be used in combination with other anti-staphylococcal antibiotics.

fusidate sodium 250 mg tablet, 36

10782L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*156.33	38.30	Fucidin [CS]

■ IMATINIB

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial

Clinical criteria:

Patient must have a primary diagnosis of chronic myeloid leukaemia, AND

The condition must be in the chronic phase of chronic myeloid leukaemia, AND

The condition must be expressing the Philadelphia chromosome; OR

The condition must have the transcript BCR-ABL tyrosine kinase, AND

The treatment must be for first line therapy for this condition, AND

Patient must not have previously experienced a failure of response to the PBS-subsidised treatment with this drug for this condition; OR

Patient must have experienced intolerance, not a failure of response, to PBS-subsidised treatment with dasatinib as a first line therapy for this condition; OR

Patient must have experienced intolerance, not a failure of response, to PBS-subsidised treatment with nilotinib as a first line therapy for this condition, AND

The treatment must not exceed a total maximum of 18 months of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition, AND

The treatment must be the sole PBS-subsidised therapy for this condition.

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; 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

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.

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

Complex Drugs

Reply Paid 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 the Department of Human Services on 1800 700 270 (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.

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: First Continuing

Clinical criteria:

The condition must be in the chronic phase of chronic myeloid leukaemia, AND

Patient must have received initial PBS-subsidised treatment with this drug as a first line therapy for this condition; OR

Patient must have experienced intolerance, not a failure of response, to PBS-subsidised treatment with dasatinib as a first line therapy for this condition; OR

Patient must have experienced intolerance, not a failure of response, to PBS-subsidised treatment with nilotinib as a first line therapy for this condition, AND

Patient must have demonstrated a major cytogenic response; OR

Patient must have demonstrated a peripheral blood level of BCR-ABL of less than 1%, AND

The treatment must not exceed a total maximum of 24 weeks of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, AND

The treatment must be the sole PBS-subsidised therapy for this condition.

First continuing applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a response to treatment as evidenced by either:

(a) 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].

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

Complex Drugs

Reply Paid 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. 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 the Department of Human Services on 1800 700 270 (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.

2. 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.

3. 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.

4. 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).

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.

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Subsequent continuing

Clinical criteria:

The condition must be in the chronic phase of chronic myeloid leukaemia, AND

Patient must have received initial continuing PBS-subsidised treatment with this drug as a first line therapy for this condition; OR

Patient must have experienced intolerance, not a failure of response, to PBS-subsidised treatment with dasatinib as a first line therapy for this condition; OR

Patient must have experienced intolerance, not a failure of response, to PBS-subsidised treatment with nilotinib as a first line therapy for this condition, AND

Patient must have maintained a major cytogenetic response; OR

Patient must have maintained a peripheral blood level of BCR-ABL of less than 1%, AND

The treatment must not exceed a total maximum of 24 weeks of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Second and subsequent authority applications for continuing therapy with imatinib mesylate may be made on the 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).

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. 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 the Department of Human Services on 1800 700 270 (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.

2. 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.

3. 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.

4. 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).

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.

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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

imatinib 100 mg tablet, 60

9113P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1862.59	38.30	Glivec [NV]

imatinib 400 mg tablet, 30

9114Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3598.23	38.30	Glivec [NV]

■ MILK POWDER SYNTHETIC LOW CALCIUM

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.

Restricted benefit

Hypercalcaemia

Population criteria:


Patient must be under the age of 4 years.

milk powder synthetic low calcium oral liquid: powder for, 400 g


3092R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	8	5	..	*355.17	38.30	Locasol [SB]

■ NALOXONE

naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules

10783M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	95.41	38.30	Naloxone Hydrochloride (DBL) [HH]

naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules

10787R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	95.41	38.30	Naloxone Hydrochloride (DBL) [HH]

■ PHENOXYBENZAMINE

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.

Restricted benefit

Phaeochromocytoma

Restricted benefit

Neurogenic urinary retention

phenoxybenzamine hydrochloride 10 mg capsule, 100

1862B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	1102.60	38.30	Dibenylene [GH]

phenoxybenzamine hydrochloride 10 mg capsule, 100

9286R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	1102.60	38.30	Dibenzylene [BZ]

phenoxybenzamine hydrochloride 10 mg capsule, 30

1166J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	..	*997.08	38.30	Amdipharm Mercury (Australia) Pty Limited [GH]

■ POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL

Authority required (STREAMLINED)

6172

Severe dry eye syndrome

Clinical criteria:

Patient must be sensitive to preservatives in multi-dose eye drops.

polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses

5532E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	2	5	..	*33.29	34.46	Systane [AQ]

polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses

9170P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*33.29	34.46	Systane [AQ]

■ PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES

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)

6174

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.

Authority required (STREAMLINED)

6193

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.

Authority required (STREAMLINED)

6204

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 must be documented in the patient's medical records

Authority required (STREAMLINED)

6137

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 must be documented in the patient's medical records

Authority required (STREAMLINED)

6182

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 must be documented in the patient's medical records

Authority required (STREAMLINED)

6194

Biliary atresia

Authority required (STREAMLINED)

6157

Chronic liver failure with fat malabsorption

Authority required (STREAMLINED)

6205

Chylous ascites

Authority required (STREAMLINED)

6195

Cystic fibrosis

Authority required (STREAMLINED)

6158

Enterokinase deficiency

Authority required (STREAMLINED)

6166

Proven fat malabsorption

Authority required (STREAMLINED)

6148

Severe diarrhoea of greater than 2 weeks duration

Population criteria:

Patient must be aged less than 4 months.

Authority required (STREAMLINED)

6138

Severe intestinal malabsorption including short bowel syndrome

protein hydrolysate formula with medium chain triglycerides oral liquid: powder for, 450 g

8259Q



Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8	5	..	*99.73	38.30	Aptamil Gold+ Pepti-Junior [NU]

▪ PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES

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)

6174

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.

Authority required (STREAMLINED)

6193

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.

Authority required (STREAMLINED)

6204

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 must be documented in the patient's medical records

Authority required (STREAMLINED)

6137

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 must be documented in the patient's medical records

Authority required (STREAMLINED)

6182

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 must be documented in the patient's medical records

Authority required (STREAMLINED)

6194

Biliary atresia

Authority required (STREAMLINED)

6157

Chronic liver failure with fat malabsorption

Authority required (STREAMLINED)

6205

Chylous ascites

Authority required (STREAMLINED)

6195

Cystic fibrosis

Authority required (STREAMLINED)

6158

Enterokinase deficiency

Authority required (STREAMLINED)

6166

Proven fat malabsorption

Authority required (STREAMLINED)

6148

Severe diarrhoea of greater than 2 weeks duration

Population criteria:

Patient must be aged less than 4 months.

Authority required (STREAMLINED)

6138

Severe intestinal malabsorption including short bowel syndrome

Authority required (STREAMLINED)

6206

Chylothorax

protein hydrolysate formula with medium chain triglycerides oral liquid: powder for, 400 g

2676W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*153.41	38.30	Alfaré [NT]

▪ **RANITIDINE**

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

Note Pharmaceutical benefits that have the form ranitidine tablet 150 mg (as hydrochloride) and pharmaceutical benefits that have the form ranitidine tablet, effervescent, 150 mg (as hydrochloride) are equivalent for the purposes of substitution.

ranitidine 150 mg tablet, 60

1978D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	1	5	..	14.56	15.73	^a APO-Ranitidine [TX] ^a Chem mart Ranitidine [CH] ^a Rani 2 [AF] ^a Ranitidine GH [GQ] ^a Ranoxyl [FM]	^a Ausran [RW] ^a GenRx Ranitidine [GX] ^a Ranitidine AN [EA] ^a Ranitidine Sandoz [SZ] ^a Terry White Chemists Ranitidine [TW]
			^b 2.00	16.56	15.73	^a Ulcaid [RA] ^a Zantac [AS]	

ranitidine 150 mg tablet: effervescent, 30

1937Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	^b 1.40	*16.49	16.26	^a Zantac [AS]

▪ **RITUXIMAB**

Note A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

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

Authority required (STREAMLINED)

6161

Stage III or IV CD20 positive follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Maintenance therapy

Clinical criteria:

Patient must have demonstrated a partial or complete response to induction treatment with either R-CHOP or R-CVP regimens for previously untreated follicular B-cell Non-Hodgkin's lymphoma, received immediately prior to this current Authority application, AND

Patient must not have received bendamustine induction therapy, AND

The treatment must be maintenance therapy, AND

Patient must not receive more than 12 doses or 2 years duration of treatment, whichever comes first, under this restriction.

rituximab 1.4 g/11.7 mL injection, 11.7 mL vial

10742J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	11	..	2850.65	38.30	Mabthera SC [RO]

▪ RITUXIMAB

Note A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

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

Authority required (STREAMLINED)

6187

Previously untreated aggressive CD20 positive non-Hodgkin's lymphoma

Treatment Phase: Induction treatment

Clinical criteria:

The treatment must be in combination with PBS-subsidised chemotherapy, AND

The condition must be previously untreated, AND

The treatment must be for induction treatment purposes only, AND

Patient must not be eligible for stem cell transplantation if they have mantle cell lymphoma.

An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab with no more than 8 doses in total.

Authority required (STREAMLINED)

6162

Previously untreated symptomatic indolent CD20 positive non-Hodgkin's lymphoma in combination with chemotherapy

Treatment Phase: Induction treatment

Clinical criteria:

The treatment must be in combination with PBS-subsidised chemotherapy, AND

The condition must be previously untreated, AND

The condition must be symptomatic, AND

The treatment must be for induction treatment purposes only, AND

Patient must not receive more than the number of cycles of treatment recommended by standard guidelines for the partner chemotherapy under this restriction.

An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab with no more than 8 doses in total.

rituximab 1.4 g/11.7 mL injection, 11.7 mL vial

10719E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	6	..	2850.65	38.30	Mabthera SC [RO]

▪ SODIUM HYALURONATE

Note The in-use shelf life of Hylo-Fresh and Hylo-Forte is 6 months from the date of opening.

Authority required (STREAMLINED)

4105

Severe dry eye syndrome

Clinical criteria:

Patient must be sensitive to preservatives in multi-dose eye drops.

sodium hyaluronate 0.1% (1 mg/mL) eye drops, 10 mL

2184Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	5	..	34.07	35.24	Hylo-Fresh [AE]

sodium hyaluronate 0.2% (2 mg/mL) eye drops, 10 mL

2171G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	‡1	5	..	34.07	35.24	Hylo-Forte [AE]

▪ SOY LECITHIN + TOCOPHEROLS + VITAMIN A

Authority required (STREAMLINED)

6172

Severe dry eye syndrome

Clinical criteria:

Patient must be sensitive to preservatives in multi-dose eye drops.

soy lecithin 1% + tocopherols 0.002% + vitamin A palmitate 0.025% eye spray, 100 actuations

5545W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	2	5	..	*34.93	36.10	tearsagain [RB]

soy lecithin 1% + tocopherols 0.002% + vitamin A palmitate 0.025% eye spray, 100 actuations

9448G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*34.93	36.10	tearsagain [RB]

▪ TRIGLYCERIDES MEDIUM CHAIN

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)

6147

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.

Authority required (STREAMLINED)

6191

Dietary management of conditions requiring a source of medium chain triglycerides

Clinical criteria:

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.

triglycerides medium chain oral liquid, 18 x 250 mL cartons

10049X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*357.19	38.30	betaquik [VF]

▪ TRIGLYCERIDES MEDIUM CHAIN

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)

6181

Chylous ascites

Authority required (STREAMLINED)

6134

Chylothorax

Authority required (STREAMLINED)

6164

Fat malabsorption

Clinical criteria:

The condition must be due to liver disease; OR

The condition must be due to short gut syndrome; OR

The condition must be due to cystic fibrosis; OR

The condition must be due to gastrointestinal disorders.

Authority required (STREAMLINED)

6203

Hyperlipoproteinaemia type 1

Authority required (STREAMLINED)

6155

Intractable childhood epilepsy

Clinical criteria:

Patient must require a ketogenic diet.

Authority required (STREAMLINED)

6135

Cerebrospinal fluid glucose transporter defect

Clinical criteria:

Patient must require a ketogenic diet.

Authority required (STREAMLINED)

6146

Long chain fatty acid oxidation disorders

triglycerides medium chain oil: oral, 500 mL

3128P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*49.83	38.30	MCT Oil [SB]

triglycerides medium chain oral liquid, 250 mL bottle

9327X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*191.01	38.30	Liquigen [SB]

▪ TRIGLYCERIDES MEDIUM CHAIN FORMULA

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 Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

Authority required (STREAMLINED)

6165

Chylous ascites

Authority required (STREAMLINED)

6192

Chylothorax

Authority required (STREAMLINED)

6173

Fat malabsorption

Clinical criteria:

The condition must be due to liver disease; OR

The condition must be due to short gut syndrome; OR

The condition must be due to cystic fibrosis; OR

The condition must be due to gastrointestinal disorders.

Authority required (STREAMLINED)

6156

Hyperlipoproteinaemia type 1

Authority required (STREAMLINED)

6136

Long chain fatty acid oxidation disorders

triglycerides medium chain formula oral liquid: powder for, 30 x 16 g sachets

9383W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*229.49	38.30	MCT Pro-Cal [VF]

▪ TRIMETHOPRIM

Restricted benefit

Prostatitis

trimethoprim 300 mg tablet, 7

10785P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	*17.21	18.38	^a Alprim [AF]
			^B 6.60	*23.81	18.38	^a Triprim [RW]

▪ TRIMETHOPRIM + SULFAMETHOXAZOLE

Caution There is an increased risk of severe adverse reactions with this combination in the elderly.

Authority required (STREAMLINED)

6201

Prophylaxis of Pneumocystis jiroveci pneumonia

trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10

10784N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	2	..	*17.76	18.93	^a Bactrim DS [RO]	^a Resprim Forte [AF]
			^B 10.17	*27.93	18.93	^a Septrin Forte [RW]	

▪ VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE

Note FruitiVits must only be used under strict supervision of a dietitian and a paediatrician.

Restricted benefit

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.

vitamins, minerals and trace elements with carbohydrate oral liquid: powder for, 30 x 6 g sachets

10149E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	274.02	38.30	FruitiVits [VF]

▪ **VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE**

Note Paediatric Seravit must only be used under strict supervision of a dietitian and a paediatrician.

Restricted benefit

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 an infant or a child.

vitamins, minerals and trace elements with carbohydrate oral liquid: powder for, 200 g

9328Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	6	5	..	*363.93	38.30	Paediatric Seravit [SB]

▪ **WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, LONG CHAIN POLYUNSATURATED FATTY ACIDS, VITAMINS AND MINERALS, LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE**

Authority required (STREAMLINED)

6190

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.

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

9382T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	9	5	..	*1406.25	38.30	RenaStart [VF]

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

2870C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*1499.49	38.30	Renastart [VF]

▪ **WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, VITAMINS AND MINERALS, AND LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE**

Authority required (STREAMLINED)

6190

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.

whey protein formula supplemented with amino acids, vitamins and minerals, and low in protein, phosphate, potassium and lactose oral liquid: powder for, 400 g

8587Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	16	5	..	*1007.25	38.30	Kindergen [SB]

Palliative Care

▪ BENZDAMINE

Authority required (STREAMLINED)

6197

Painful mouth

Clinical criteria:

Patient must be receiving palliative care.

benzdamine hydrochloride 0.15% mouthwash, 500 mL

5385K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	3	..	23.51	24.68	Difflam [IA]

▪ BISACODYL

Restricted benefit

Constipation

Clinical criteria:

Patient must be receiving palliative care.

bisacodyl 10 mg suppository, 10

5303D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	3	..	*23.04	24.21	^a Petrus Bisacodyl Suppositories [PP]
			^B 1.29	*24.33	24.21	^a Dulcolax [BY]

bisacodyl 10 mg suppository, 12

5304E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	3	..	*20.76	21.93	Petrus Bisacodyl Suppositories [PP]

bisacodyl 10 mg/5 mL enema, 25 x 5 mL

5302C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	3	..	37.83	38.30	Bisalax [AS]

bisacodyl 5 mg tablet: enteric, 200

5301B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	17.11	18.28	Lax-Tab [AE]

▪ CLONAZEPAM

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

Authority required

Myoclonus

Clinical criteria:

The treatment must be for prophylaxis or prevention of the indication, AND

Patient must be receiving palliative care.

clonazepam 2 mg tablet, 100

5338Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	21.13	22.30	^a Paxam 2 [AF]
			^B 1.68	22.81	22.30	^a Rivotril [RO]

clonazepam 2.5 mg/mL oral liquid, 10 mL

5339B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*17.93	19.10	Rivotril [RO]

clonazepam 500 microgram tablet, 100

5337X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	16.11	17.28	^a Paxam 0.5 [AF]
			^b 1.48	17.59	17.28	^a Rivotril [RO]

▪ DIAZEPAM

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

Authority required

Anxiety

Clinical criteria:

Patient must be receiving palliative care.

diazepam 2 mg tablet, 50

5355W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	11.43	12.60	^a Antenex 2 [AF]	^a APO-Diazepam [TX]
						^a Ranzepam [RA]	^a Valpam 2 [RW]

diazepam 5 mg tablet, 50

5356X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	11.53	12.70	^a Antenex 5 [AF]	^a APO-Diazepam [TX]
						^a Ranzepam [RA]	^a Valpam 5 [RW]
						^b 2.19	13.72

▪ DICLOFENAC

Restricted benefit

Severe pain

Clinical criteria:

Patient must be receiving palliative care.

diclofenac sodium 100 mg suppository, 20

5363G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*26.85	28.02	Voltaren 100 [NV]

diclofenac sodium 25 mg tablet: enteric, 50

5361E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	3	..	*13.79	14.96	^a APO-Diclofenac [TX]	^a Chem mart Diclofenac [CH]
						^a Clonac 25 [RW]	^a Diclofenac AN [EA]
						^a Diclofenac-GA [ED]	^a Diclofenac Sandoz [SZ]
						^a Fenac 25 [AF]	^a Terry White Chemists Diclofenac [TW]
						^b 2.44	*16.23

diclofenac sodium 50 mg tablet: enteric, 50

5362F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	12.75	13.92	^a APO-Diclofenac [TX]	^a Chem mart Diclofenac [CH]
						^a Clonac 50 [RW]	^a Diclofenac AN [EA]
						^a Diclofenac-GA [ED]	^a Diclofenac Sandoz [SZ]
						^a Fenac [AF]	^a Terry White Chemists Diclofenac [TW]
						^b 2.45	15.20

▪ HYOSCINE BUTYLBROMIDE

Authority required (STREAMLINED)

6207

For use in patients receiving palliative care

hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules

5317W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	6	3	..	*98.61	38.30	Buscopan [BY]

▪ IBUPROFEN

Restricted benefit

Severe pain

Clinical criteria:

Patient must be receiving palliative care.

ibuprofen 400 mg tablet, 30

5368M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	3	..	*17.28	18.45	Brufen [GO]

■ INDOMETHACIN**Restricted benefit**

Severe pain

Clinical criteria:

Patient must be receiving palliative care.

indomethacin 100 mg suppository, 20

5378C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*24.41	25.58	Indocid [AS]

indomethacin 25 mg capsule, 50

5377B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*16.03	17.20	^a Arthrexin [AF]
			^B 4.04	*20.07	17.20	^a Indocid [AS]

■ MACROGOL-3350

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.

Authority required (STREAMLINED)**6170**

Constipation

Clinical criteria:

Patient must be receiving palliative care.

macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets

2351R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*30.97	32.14	^a Herron ClearLax [ON]

macrogol-3350 1 g/g oral liquid: powder for, 510 g

5426N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*30.97	32.14	^a OsmoLax [KY]

■ MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDE**Authority required (STREAMLINED)****6171**

Constipation

Clinical criteria:

Patient must be receiving palliative care.

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

5389P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	3	..	*30.97	32.14	^a APO-MACROGOL plus ELECTROLYTES [TX]	^a Chemists' Own Macrogol with Electrolytes [RW]
						^a LaxaCon [EA]	^a lax-sachets [AE]
						^a Macrovic [RF]	^a Molaxole [HM]
						^a Movicol [NE]	

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

10127B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*24.13	25.30	Movicol Liquid [NE]

■ METHYLNALTREXONE**Authority required (STREAMLINED)****6180**

Opioid-induced constipation

Clinical criteria:

The treatment must be in combination with oral laxatives, AND

Patient must be receiving palliative care, AND

Patient must have failed to respond to laxatives.

METHYLNALTREXONE Solution for injection containing methylNaltrexone bromide 12 mg in 0.6 mL, 7

5424L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	263.13	38.30	Relistor [LM]

methylNaltrexone bromide 12 mg/0.6 mL injection, 0.6 mL vial

5423K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	7	*263.13	38.30	Relistor [LM]

■ MORPHINE**Caution** The risk of drug dependence is high.**Note** Telephone approvals are limited to 1 month's therapy.**Authority required**

Chronic severe disabling pain

Clinical criteria:

Patient must be receiving palliative care, AND

The condition must be unresponsive to non-opioid analgesics.

morphine sulfate 200 mg tablet: modified release, 28

5391R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	115.81	38.30	MS Contin [MF]

■ MORPHINE**Caution** The risk of drug dependence is high.**Note** Telephone approvals are limited to 1 month's therapy.**Authority required**

Severe disabling pain

Clinical criteria:

Patient must be receiving palliative care, AND

The condition must be unresponsive to non-opioid analgesics.

morphine sulfate 10 mg tablet, 20

5393W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	17.84	19.01	Sevredol [MF]

morphine sulfate 20 mg tablet, 20

5394X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	18.66	19.83	Sevredol [MF]

■ NAPROXEN**Restricted benefit**

Severe pain

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.

naproxen 125 mg/5 mL oral liquid, 474 mL

5397C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	3	..	120.60	38.30	Phebra Naproxen Suspension [PL]

■ NAPROXEN**Restricted benefit**

Severe pain

Clinical criteria:

Patient must be receiving palliative care.

naproxen 1 g tablet: modified release, 28

5348L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	16.98	18.15	^a Proxen SR 1000 [IY]
			^B 1.12	18.10	18.15	^a Naprosyn SR1000 [IX]

naproxen 250 mg tablet, 50

5345H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*17.69	18.86	^a Inza 250 [AF]
			^B 2.24	*19.93	18.86	^a Naprosyn [IX]

naproxen 500 mg tablet, 50

5346J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	15.79	16.96	^a Inza 500 [AF]
			^B 1.12	16.91	16.96	^a Naprosyn [IX]

naproxen 750 mg tablet: modified release, 28

5347K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	15.34	16.51	^a Proxen SR 750 [IY]
			^B 1.06	16.40	16.51	^a Naprosyn SR750 [IX]

▪ **NAPROXEN**

Note Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

Restricted benefit

Severe pain

Clinical criteria:

Patient must be receiving palliative care.

naproxen sodium 550 mg tablet, 50

5353R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	15.94	17.11	^a Crysanal [IY]
			^B 1.89	17.83	17.11	^a Anaprox 550 [IX]

▪ **NITRAZEPAM**

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

Authority required

Insomnia

Clinical criteria:

Patient must be receiving palliative care.

nitrazepam 5 mg tablet, 25

5359C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*13.65	14.82	^a Alodorm [AF]
			^B 2.48	*16.13	14.82	^a Mogadon [IA]

▪ **OXAZEPAM**

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

Authority required

Anxiety

Clinical criteria:

Patient must be receiving palliative care.

oxazepam 15 mg tablet, 25

5371Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*13.27	14.44	^a Alepam 15 [AF]
			^B 5.32	*18.59	14.44	^a Serepax [QA]

oxazepam 30 mg tablet, 25

5372R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	3	..	*12.59	13.76	^a Alepam 30 [AF]	^a APO-Oxazepam [TX]
						^a Murelax [RW]	
						^B 4.66	*17.25

▪ **PARACETAMOL**

Restricted benefit

Analgesia or fever

Clinical criteria:

Patient must be receiving palliative care, AND

Patient must be intolerant to alternative therapy.

paracetamol 500 mg suppository, 24

5319Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	3	..	*81.37	38.30	Panadol [GC]

paracetamol 665 mg tablet: modified release, 96

5343F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*17.89	19.06	Osteomol 665 Paracetamol [CR]

▪ **RHAMNUS FRANGULA + STERCULIA**

Restricted benefit

Constipation

Clinical criteria:

Patient must be receiving palliative care.

rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g

5322D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	3	..	26.90	28.07	Normacol Plus [NE]

▪ **SORBITOL + CITRIC ACID + LAURYL SULFOACETATE SODIUM**

Restricted benefit

Constipation

Clinical criteria:

Patient must be receiving palliative care.

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

5331N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	3	..	*32.91	34.08	^a Micolette [AE]	^a Microlax [JT]

▪ **TEMAZEPAM**

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

Authority required

Insomnia

Clinical criteria:

Patient must be receiving palliative care.

temazepam 10 mg tablet, 25

5375X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	3	..	*12.05	13.22	^a APO-Temazepam [TX]	^a Temaze [AF]
						^a Temtabs [FM]	
			^b 6.96	*19.01	13.22	^a Normison [QA]	

Highly Specialised Drugs Program (Private Hospital)

▪ AZACITIDINE

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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Myelodysplastic syndrome

Treatment Phase: Initial treatment

Clinical criteria:

The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); OR

The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS).

Classification of the condition as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations:

- a. 11% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 0 to 1 cytopenias; OR
- b. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR
- c. 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
- d. 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
- e. 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; OR
- f. Less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias.

Classification of the condition as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations:

- a. 21% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
- b. 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
- c. 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
- d. 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; and
- (d) a copy of the full blood examination report; and
- (e) 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 3 cycles will be authorised.

Authority required

Chronic Myelomonocytic Leukaemia

Treatment Phase: Initial treatment

Clinical criteria:

The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder.

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 chronic myelomonocytic leukaemia ; and
- (d) a copy of the full blood examination report; and
- (e) a signed patient acknowledgement.

No more than 3 cycles will be authorised.

Authority required

Acute Myeloid Leukaemia

Treatment Phase: Initial treatment

Clinical criteria:

The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification.

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 acute myeloid leukaemia; and
- (d) a copy of the full blood examination report; and
- (e) a signed patient acknowledgement.

No more than 3 cycles will be authorised.

azacitidine 100 mg injection, 1 vial

6100C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	14	2	..	*5219.13	^a Azadine [RZ]	^a Vidaza [CJ]

▪ **AZACITIDINE**

Note 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).

Authority required

Myelodysplastic syndrome

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); OR

The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS), AND

Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND

Patient must not have progressive disease.

Applications for continuing therapy may be made by telephone.

Up to 6 cycles will be authorised.

Authority required

Chronic Myelomonocytic Leukaemia

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder, AND

Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND

Patient must not have progressive disease.

Applications for continuing therapy may be made by telephone.

Up to 6 cycles will be authorised.

Authority required

Acute Myeloid Leukaemia

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification, AND

Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND

Patient must not have progressive disease.

Applications for continuing therapy may be made by telephone.

Up to 6 cycles will be authorised.

azacitidine 100 mg injection, 1 vial

6138C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	14	5	..	*5219.13	^a Azadine [RZ]	^a Vidaza [CJ]

▪ **LEVODOPA + CARBIDOPA ANHYDROUS**

Note Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

Note 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.

Authority required

Advanced Parkinson disease

Clinical criteria:

Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, AND

The treatment must be commenced in a hospital-based movement disorder clinic.

levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL

9744W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*11582.93	Duodopa [VE]

■ OMALIZUMAB

Note Special Pricing Arrangements apply.

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 30 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

(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

Complex Drugs

Reply Paid 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).

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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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.

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

Complex Drugs

Reply Paid 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).

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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

omalizumab 150 mg/mL injection, 1 mL syringe

10122R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	433.33	Xolair [NV]

omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

10110D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	220.13	Xolair [NV]

Highly Specialised Drugs Program (Public Hospital)

▪ AZACITIDINE

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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Myelodysplastic syndrome

Treatment Phase: Initial treatment

Clinical criteria:

The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); OR

The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS).

Classification of the condition as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations:

- a. 11% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 0 to 1 cytopenias; OR
- b. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR
- c. 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
- d. 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
- e. 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; OR
- f. Less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias.

Classification of the condition as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations:

- a. 21% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
- b. 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
- c. 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
- d. 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; and
- (d) a copy of the full blood examination report; and
- (e) 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 3 cycles will be authorised.

Authority required

Chronic Myelomonocytic Leukaemia

Treatment Phase: Initial treatment

Clinical criteria:

The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder.

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 chronic myelomonocytic leukaemia ; and
- (d) a copy of the full blood examination report; and
- (e) a signed patient acknowledgement.

No more than 3 cycles will be authorised.

Authority required

Acute Myeloid Leukaemia

Treatment Phase: Initial treatment

Clinical criteria:

The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification.

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 acute myeloid leukaemia; and
- (d) a copy of the full blood examination report; and
- (e) a signed patient acknowledgement.

No more than 3 cycles will be authorised.

azacitidine 100 mg injection, 1 vial

9597D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	14	2	..	*5172.16	^a Azadine [RZ]	^a Vidaza [CJ]

▪ **AZACITIDINE**

Note 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).

Authority required

Myelodysplastic syndrome

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); OR

The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS), AND

Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND

Patient must not have progressive disease.

Applications for continuing therapy may be made by telephone.

Up to 6 cycles will be authorised.

Authority required

Chronic Myelomonocytic Leukaemia

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder, AND

Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND

Patient must not have progressive disease.

Applications for continuing therapy may be made by telephone.

Up to 6 cycles will be authorised.

Authority required

Acute Myeloid Leukaemia

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification, AND

Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND

Patient must not have progressive disease.

Applications for continuing therapy may be made by telephone.

Up to 6 cycles will be authorised.

azacitidine 100 mg injection, 1 vial

9598E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	14	5	..	*5172.16	^a Azadine [RZ]	^a Vidaza [CJ]

▪ **LEVODOPA + CARBIDOPA ANHYDROUS**

Note Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

Note 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.

Authority required (STREAMLINED)

6179

Advanced Parkinson disease

Clinical criteria:

Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, AND

The treatment must be commenced in a hospital-based movement disorder clinic.

levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL

9743T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*11536.00	Duodopa [VE]

■ OMALIZUMAB**Note** Special Pricing Arrangements apply.**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 30 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

(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

Complex Drugs

Reply Paid 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).

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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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.

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

Complex Drugs

Reply Paid 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).

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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

omalizumab 150 mg/mL injection, 1 mL syringe

10109C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	410.00	Xolair [NV]

omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

10118M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	205.00	Xolair [NV]

Repatriation Pharmaceutical Benefits Scheme

■ GLYCEROL

glycerol 1.4 g suppository, 12

10596Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*22.65	6.20	Petrus Pharmaceuticals Pty Ltd [PP]

glycerol 2.8 g suppository, 12

4246L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*23.13	6.20	Petrus Pharmaceuticals Pty Ltd [PP]

glycerol 700 mg suppository, 12

10586E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*22.29	6.20	Petrus Pharmaceuticals Pty Ltd [PP]