



Australian Government

Department of Health



Schedule of Pharmaceutical Benefits

Summary of Changes

Effective 1 November 2016



Fees, Patient Contributions and Safety Net Thresholds

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

Dispensing Fees:	Ready-prepared	\$7.02
	Dangerous drug fee	\$2.95
	Extemporaneously-prepared	\$9.06
	Allowable additional patient charge*	\$4.33
Additional Fees (for safety net prices):	Ready-prepared	\$1.19
	Extemporaneously-prepared	\$1.55
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 November 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

Deletions

Deletion – Brand

- 3496B *Pharmacor Salbutamol 2.5, CR* – **SALBUTAMOL**, salbutamol 2.5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules
- 3497C *Pharmacor Salbutamol 5, CR* – **SALBUTAMOL**, salbutamol 5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules

General Pharmaceutical Benefits

Additions

Addition – Item

- 10934L **AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE AND TYROSINE**, amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine and tyrosine oral liquid: powder for, 30 x 34 g bottles (*TYR Easy Shake & Go*)
- 10922W **ARMODAFINIL**, armodafinil 50 mg tablet, 30 (*Nuvigil*)
- 10912H **ARMODAFINIL**, armodafinil 150 mg tablet, 30 (*Nuvigil*)
- 10919Q **ARMODAFINIL**, armodafinil 250 mg tablet, 30 (*Nuvigil*)
- 10932J **AURANOFIN**, auranofin 3 mg tablet, 100 (*Ridaura*)
- 10943Y **DEXAMETHASONE**, dexamethasone 700 microgram implant, 1 (*Ozurdex*)
- 10915L **IMATINIB**, imatinib 100 mg capsule, 60 (*IMATINIB-DRLA*)
- 10918P **IMATINIB**, imatinib 100 mg capsule, 60 (*IMATINIB-DRLA*)
- 10920R **IMATINIB**, imatinib 100 mg capsule, 60 (*IMATINIB-DRLA*)
- 10924Y **IMATINIB**, imatinib 100 mg capsule, 60 (*IMATINIB-DRLA*)
- 10940T **IMATINIB**, imatinib 100 mg capsule, 60 (*IMATINIB-DRLA*)
- 10941W **IMATINIB**, imatinib 100 mg capsule, 60 (*IMATINIB-DRLA*)
- 10942X **IMATINIB**, imatinib 100 mg capsule, 60 (*IMATINIB-DRLA*)
- 10916M **IMATINIB**, imatinib 400 mg capsule, 30 (*IMATINIB-DRLA*)
- 10917N **IMATINIB**, imatinib 400 mg capsule, 30 (*IMATINIB-DRLA*)
- 10921T **IMATINIB**, imatinib 400 mg capsule, 30 (*IMATINIB-DRLA*)
- 10925B **IMATINIB**, imatinib 400 mg capsule, 30 (*IMATINIB-DRLA*)
- 10933K **IMATINIB**, imatinib 400 mg capsule, 30 (*IMATINIB-DRLA*)
- 10935M **IMATINIB**, imatinib 400 mg capsule, 30 (*IMATINIB-DRLA*)
- 10939R **IMATINIB**, imatinib 400 mg capsule, 30 (*IMATINIB-DRLA*)
- 1703P **PHENOXYMETHYLPENICILLIN**, phenoxymethylpenicillin 250 mg tablet, 25 (*Aspecillin VK*)
- 1787C **PHENOXYMETHYLPENICILLIN**, phenoxymethylpenicillin 250 mg tablet, 25 (*Aspecillin VK*)

3360W	PHENOXYMETHYLPENICILLIN , phenoxymethylpenicillin 250 mg tablet, 25 (<i>Aspecillin VK</i>) (Dental)
3028J	PHENOXYMETHYLPENICILLIN , phenoxymethylpenicillin 500 mg tablet, 25 (<i>Aspecillin VK</i>)
3361X	PHENOXYMETHYLPENICILLIN , phenoxymethylpenicillin 500 mg tablet, 25 (<i>Aspecillin VK</i>) (Dental)
10928E	RIBAVIRIN , ribavirin 200 mg tablet, 28 (<i>Ibavyr</i>)
10937P	RIBAVIRIN , ribavirin 200 mg tablet, 28 (<i>Ibavyr</i>)
10913J	RUXOLITINIB , ruxolitinib 10 mg tablet, 56 (<i>Jakavi</i>)
10927D	RUXOLITINIB , ruxolitinib 10 mg tablet, 56 (<i>Jakavi</i>)

Addition – Brand

8213G	<i>Atorvastatin Amneal, EF</i> – ATORVASTATIN , atorvastatin 10 mg tablet, 30
9230T	<i>Atorvastatin Amneal, EF</i> – ATORVASTATIN , atorvastatin 10 mg tablet, 30
8214H	<i>Atorvastatin Amneal, EF</i> – ATORVASTATIN , atorvastatin 20 mg tablet, 30
9231W	<i>Atorvastatin Amneal, EF</i> – ATORVASTATIN , atorvastatin 20 mg tablet, 30
8215J	<i>Atorvastatin Amneal, EF</i> – ATORVASTATIN , atorvastatin 40 mg tablet, 30
9232X	<i>Atorvastatin Amneal, EF</i> – ATORVASTATIN , atorvastatin 40 mg tablet, 30
8521L	<i>Atorvastatin Amneal, EF</i> – ATORVASTATIN , atorvastatin 80 mg tablet, 30
9233Y	<i>Atorvastatin Amneal, EF</i> – ATORVASTATIN , atorvastatin 80 mg tablet, 30
10241B	<i>Desvenlafaxine Sandoz, SZ</i> – DESVENLAFAXINE , desvenlafaxine 50 mg modified release tablet, 28
10231L	<i>Desvenlafaxine Sandoz, SZ</i> – DESVENLAFAXINE , desvenlafaxine 100 mg modified release tablet, 28
9155W	<i>DYTREX 30, RW</i> – DULOXETINE , duloxetine 30 mg enteric capsule, 28
9156X	<i>DYTREX 60, RW</i> – DULOXETINE , duloxetine 60 mg enteric capsule, 28
8700X	<i>Blooms The Chemist Escitalopram, IB</i> – ESCITALOPRAM , escitalopram 10 mg tablet, 28
8701Y	<i>Blooms The Chemist Escitalopram, IB</i> – ESCITALOPRAM , escitalopram 20 mg tablet, 28
1434L	<i>Blooms the Chemist Fluoxetine, IB</i> – FLUOXETINE , fluoxetine 20 mg capsule, 28
8505P	<i>GAPENTIN, RF</i> – GABAPENTIN , gabapentin 100 mg capsule, 100
1834M	<i>GAPENTIN, RF</i> – GABAPENTIN , gabapentin 300 mg capsule, 100
8559L	<i>GAPENTIN, RF</i> – GABAPENTIN , gabapentin 600 mg tablet, 100
8389M	<i>GAPENTIN, RF</i> – GABAPENTIN , gabapentin 800 mg tablet, 100
1970Q	<i>ACQUIN, RF</i> – QUINAPRIL , quinapril 20 mg tablet, 30

Deletions

Deletion – Brand

2600W	<i>GenRx Allopurinol, GX</i> – ALLOPURINOL , allopurinol 100 mg tablet, 200
2604C	<i>GenRx Allopurinol, GX</i> – ALLOPURINOL , allopurinol 300 mg tablet, 60
1891M	<i>Pharmacor AmoxyClav 500/125, CR</i> – AMOXYCILLIN + CLAVULANIC ACID , amoxycillin 500 mg + clavulanic acid 125 mg tablet, 10
5008N	<i>Pharmacor AmoxyClav 500/125, CR</i> – AMOXYCILLIN + CLAVULANIC ACID , amoxycillin 500 mg + clavulanic acid 125 mg tablet, 10 (Dental)
8179L	<i>Pharmacor Anastrozole 1, CR</i> – ANASTROZOLE , anastrozole 1 mg tablet, 30
8295N	<i>Pharmacor Candesartan 4, CR</i> – CANDESARTAN , candesartan cilexetil 4 mg tablet, 30
8296P	<i>Pharmacor Candesartan 8, CR</i> – CANDESARTAN , candesartan cilexetil 8 mg tablet, 30
8297Q	<i>Pharmacor Candesartan 16, CR</i> – CANDESARTAN , candesartan cilexetil 16 mg tablet, 30
8889W	<i>Pharmacor Candesartan 32, CR</i> – CANDESARTAN , candesartan cilexetil 32 mg tablet, 30
8504N	<i>Pharmacor Candesartan HCT 16/12.5, CR</i> – CANDESARTAN + HYDROCHLOROTHIAZIDE , candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30
9314F	<i>Pharmacor Candesartan HCT 32/12.5, CR</i> – CANDESARTAN + HYDROCHLOROTHIAZIDE , candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30

9315G	<i>Pharmacor Candesartan HCT 32/25, CR – CANDESARTAN + HYDROCHLOROTHIAZIDE, candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30</i>
1209P	<i>Ciprofloxacin 500, CR – CIPROFLOXACIN, ciprofloxacin 500 mg tablet, 14</i>
1210Q	<i>Ciprofloxacin 750, CR – CIPROFLOXACIN, ciprofloxacin 750 mg tablet, 14</i>
2532G	<i>Pharmacor Donepezil 5, CR – DONEPEZIL, donepezil hydrochloride 5 mg tablet, 28</i>
8495D	<i>Pharmacor Donepezil 5, CR – DONEPEZIL, donepezil hydrochloride 5 mg tablet, 28</i>
1434L	<i>Fluoxetine 20, CR – FLUOXETINE, fluoxetine 20 mg capsule, 28</i>
2591J	<i>Isotretinoin SCP 10, CR – ISOTRETINOIN, isotretinoin 10 mg capsule, 60</i>
2848X	<i>Lamotrusted 25, CR – LAMOTRIGINE, lamotrigine 25 mg tablet, 56</i>
2849Y	<i>Lamotrusted 50, CR – LAMOTRIGINE, lamotrigine 50 mg tablet, 56</i>
2850B	<i>Lamotrusted 100, CR – LAMOTRIGINE, lamotrigine 100 mg tablet, 56</i>
2851C	<i>Lamotrusted 200, CR – LAMOTRIGINE, lamotrigine 200 mg tablet, 56</i>
8513C	<i>GenRx Mirtazapine, GX – MIRTAZAPINE, mirtazapine 30 mg tablet, 30</i>
8627C	<i>Pharmacor Montelukast 4, CR – MONTELUKAST, montelukast 4 mg chewable tablet, 28</i>
8628D	<i>Pharmacor Montelukast 5, CR – MONTELUKAST, montelukast 5 mg chewable tablet, 28</i>
8399C	<i>I-Pantoprazole, CR – PANTOPRAZOLE, pantoprazole 20 mg enteric tablet, 30</i>
8694N	<i>Pharmacor Pioglitazone 15, CR – PIOGLITAZONE, pioglitazone 15 mg tablet, 28</i>
8695P	<i>Pharmacor Pioglitazone 30, CR – PIOGLITAZONE, pioglitazone 30 mg tablet, 28</i>
8696Q	<i>Pharmacor Pioglitazone 45, CR – PIOGLITAZONE, pioglitazone 45 mg tablet, 28</i>
2833D	<i>Pharmacor Pravastatin 10, CR – PRAVASTATIN, pravastatin sodium 10 mg tablet, 30</i>
9237E	<i>Pharmacor Pravastatin 10, CR – PRAVASTATIN, pravastatin sodium 10 mg tablet, 30</i>
2834E	<i>Pharmacor Pravastatin 20, CR – PRAVASTATIN, pravastatin sodium 20 mg tablet, 30</i>
9238F	<i>Pharmacor Pravastatin 20, CR – PRAVASTATIN, pravastatin sodium 20 mg tablet, 30</i>
8197K	<i>Pharmacor Pravastatin 40, CR – PRAVASTATIN, pravastatin sodium 40 mg tablet, 30</i>
9239G	<i>Pharmacor Pravastatin 40, CR – PRAVASTATIN, pravastatin sodium 40 mg tablet, 30</i>
2893G	<i>Pharmacor Prozac 5, CR – PROCHLORPERAZINE, prochlorperazine maleate 5 mg tablet, 25</i>
5205Y	<i>Pharmacor Prozac 5, CR – PROCHLORPERAZINE, prochlorperazine maleate 5 mg tablet, 25 (Dental)</i>
9122D	<i>Pharmacor Ramipril 5, CR – RAMIPRIL, ramipril 5 mg capsule, 30</i>
8470T	<i>Pharmacor Ramipril 10, CR – RAMIPRIL, ramipril 10 mg capsule, 30</i>
3171X	<i>Risperidone 3, CR – RISPERIDONE, risperidone 3 mg tablet, 60</i>
3172Y	<i>Risperidone 4, CR – RISPERIDONE, risperidone 4 mg tablet, 60</i>
1760P	<i>Roxithromycin SCP 150, CR – ROXITHROMYCIN, roxithromycin 150 mg tablet, 10</i>
5260W	<i>Roxithromycin SCP 150, CR – ROXITHROMYCIN, roxithromycin 150 mg tablet, 10 (Dental)</i>
5261X	<i>Roxithromycin SCP 300, CR – ROXITHROMYCIN, roxithromycin 300 mg tablet, 5 (Dental)</i>
8016X	<i>Roxithromycin SCP 300, CR – ROXITHROMYCIN, roxithromycin 300 mg tablet, 5</i>
2000G	<i>Pharmacor Salbutamol 2.5, CR – SALBUTAMOL, salbutamol 2.5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules</i>
2001H	<i>Pharmacor Salbutamol 5, CR – SALBUTAMOL, salbutamol 5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules</i>
8301X	<i>Venlafaxine SR SCP 75, CR – VENLAFAXINE, venlafaxine 75 mg modified release capsule, 28</i>
8302Y	<i>Venlafaxine SR SCP 150, CR – VENLAFAXINE, venlafaxine 150 mg modified release capsule, 28</i>

Alterations

Alteration – Restriction

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

10505X	AFLIBERCEPT , aflibercept 4 mg/0.1 mL injection, 0.1 mL vial (<i>Eylea</i>)
2168D	AFLIBERCEPT , aflibercept 4 mg/0.1 mL injection, 0.1 mL vial (<i>Eylea</i>)

5457F	DENOSUMAB , denosumab 60 mg/mL injection, 1 mL syringe (<i>Prolia</i>)
10888C	EXENATIDE , exenatide 2 mg/dose injection: modified release, 4 injection devices (<i>Bydureon</i>)
9111M	IMATINIB , imatinib 100 mg tablet, 60 (<i>Glivec</i>)
9112N	IMATINIB , imatinib 400 mg tablet, 30 (<i>Glivec</i>)
9113P	IMATINIB , imatinib 100 mg tablet, 60 (<i>Glivec</i> , <i>IMATINIB RBX</i> , <i>Imatinib-Teva</i>)
9114Q	IMATINIB , imatinib 400 mg tablet, 30 (<i>Glivec</i> , <i>IMATINIB RBX</i> , <i>Imatinib-Teva</i>)
9115R	IMATINIB , imatinib 100 mg tablet, 60 (<i>Glivec</i> , <i>IMATINIB RBX</i> , <i>Imatinib-Teva</i>)
9116T	IMATINIB , imatinib 400 mg tablet, 30 (<i>Glivec</i> , <i>IMATINIB RBX</i> , <i>Imatinib-Teva</i>)
9123E	IMATINIB , imatinib 100 mg tablet, 60 (<i>Glivec</i> , <i>IMATINIB RBX</i> , <i>Imatinib-Teva</i>)
9124F	IMATINIB , imatinib 400 mg tablet, 30 (<i>Glivec</i> , <i>IMATINIB RBX</i> , <i>Imatinib-Teva</i>)
9172R	IMATINIB , imatinib 100 mg tablet, 60 (<i>Glivec</i> , <i>IMATINIB RBX</i> , <i>Imatinib-Teva</i>)
9173T	IMATINIB , imatinib 400 mg tablet, 30 (<i>Glivec</i> , <i>IMATINIB RBX</i> , <i>Imatinib-Teva</i>)
9174W	IMATINIB , imatinib 100 mg tablet, 60 (<i>Glivec</i> , <i>IMATINIB RBX</i> , <i>Imatinib-Teva</i>)
9175X	IMATINIB , imatinib 400 mg tablet, 30 (<i>Glivec</i> , <i>IMATINIB RBX</i> , <i>Imatinib-Teva</i>)
9176Y	IMATINIB , imatinib 100 mg tablet, 60 (<i>Glivec</i> , <i>IMATINIB RBX</i> , <i>Imatinib-Teva</i>)
9177B	IMATINIB , imatinib 400 mg tablet, 30 (<i>Glivec</i> , <i>IMATINIB RBX</i> , <i>Imatinib-Teva</i>)
9178C	IMATINIB , imatinib 100 mg tablet, 60 (<i>Glivec</i> , <i>IMATINIB RBX</i>)
9179D	IMATINIB , imatinib 400 mg tablet, 30 (<i>Glivec</i> , <i>IMATINIB RBX</i>)
8816B	MODAFINIL , modafinil 100 mg tablet, 60 (<i>Modafin</i> , <i>Modavigil</i>)
2962X	NAFARELIN , nafarelin 200 microgram/actuation nasal spray, 60 actuations (<i>Synarel</i>)
10138N	RANIBIZUMAB , ranibizumab 1.65 mg/0.165 mL injection, 1 x 0.165 mL syringe (<i>Lucentis</i>)
10373Y	RANIBIZUMAB , ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial (<i>Lucentis</i>)
10374B	RANIBIZUMAB , ranibizumab 1.65 mg/0.165 mL injection, 1 x 0.165 mL syringe (<i>Lucentis</i>)
1382R	RANIBIZUMAB , ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial (<i>Lucentis</i>)
10615Q	RUXOLITINIB , ruxolitinib 15 mg tablet, 56 (<i>Jakavi</i>)
10616R	RUXOLITINIB , ruxolitinib 5 mg tablet, 56 (<i>Jakavi</i>)
10617T	RUXOLITINIB , ruxolitinib 20 mg tablet, 56 (<i>Jakavi</i>)
10767Q	USTEKINUMAB , ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial (<i>Stelara</i>)
10774C	USTEKINUMAB , ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial (<i>Stelara</i>)

Alteration – Manufacturer Code

		<i>From</i>	<i>To</i>
8853Y	<i>Alvesco 80</i> – CICLESONIDE , ciclesonide 80 microgram/actuation pressurised inhalation, 120 actuations	NQ	AP
8854B	<i>Alvesco 160</i> – CICLESONIDE , ciclesonide 160 microgram/actuation pressurised inhalation, 120 actuations	NQ	AP
8627C	<i>Lukair</i> – MONTELUKAST , montelukast 4 mg chewable tablet, 28	FR	AL
8628D	<i>Lukair</i> – MONTELUKAST , montelukast 5 mg chewable tablet, 28	FR	AL
9006B	<i>PREXUM 2.5</i> – PERINDOPRIL , perindopril arginine 2.5 mg tablet, 30	RX	RW
9007C	<i>PREXUM 5</i> – PERINDOPRIL , perindopril arginine 5 mg tablet, 30	RX	RW
9008D	<i>PREXUM 10</i> – PERINDOPRIL , perindopril arginine 10 mg tablet, 30	RX	RW
9346X	<i>Reaptan 5/5</i> – PERINDOPRIL + AMLODIPINE , perindopril arginine 5 mg + amlodipine 5 mg tablet, 30	RX	RW
9347Y	<i>Reaptan 5/10</i> – PERINDOPRIL + AMLODIPINE , perindopril arginine 5 mg + amlodipine 10 mg tablet, 30	RX	RW
9348B	<i>Reaptan 10/5</i> – PERINDOPRIL + AMLODIPINE , perindopril arginine 10 mg + amlodipine 5 mg tablet, 30	RX	RW

9349C	<i>Reaptan 10/10</i> – PERINDOPRIL + AMLODIPINE , perindopril arginine 10 mg + amlodipine 10 mg tablet, 30	RX	RW
2845R	<i>Prexum Combi 5/1.25</i> – PERINDOPRIL + INDAPAMIDE , perindopril arginine 5 mg + indapamide hemihydrate 1.25 mg tablet, 30	RX	RW

Alteration – Number of Repeats

3093T	HYDROXYUREA , hydroxyurea 500 mg capsule, 100 (<i>Hydrea</i>)	From 0	To 3
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Advance Notices

1 December 2016

Deletion – Brand

2014B	<i>Gaviscon P, RC</i> – ALGINATE SODIUM + CALCIUM CARBONATE + BICARBONATE , alginate sodium 500 mg/10 mL + calcium carbonate 160 mg/10 mL + sodium bicarbonate 267 mg/10 mL oral liquid, 500 mL
1886G	<i>Bgramin, FM</i> – AMOXYCILLIN , amoxycillin 125 mg/5 mL powder for oral liquid, 100 mL
1887H	<i>Bgramin, FM</i> – AMOXYCILLIN , amoxycillin 250 mg/5 mL powder for oral liquid, 100 mL
3302T	<i>Bgramin, FM</i> – AMOXYCILLIN , amoxycillin 125 mg/5 mL powder for oral liquid, 100 mL (Dental)
3393N	<i>Bgramin, FM</i> – AMOXYCILLIN , amoxycillin 250 mg/5 mL powder for oral liquid, 100 mL (Dental)
8213G	<i>Atorvastatin Pfizer, FZ</i> – ATORVASTATIN , atorvastatin 10 mg tablet, 30
8214H	<i>Atorvastatin Pfizer, FZ</i> – ATORVASTATIN , atorvastatin 20 mg tablet, 30
8215J	<i>Atorvastatin Pfizer, FZ</i> – ATORVASTATIN , atorvastatin 40 mg tablet, 30
8521L	<i>Atorvastatin Pfizer, FZ</i> – ATORVASTATIN , atorvastatin 80 mg tablet, 30
9230T	<i>Atorvastatin Pfizer, FZ</i> – ATORVASTATIN , atorvastatin 10 mg tablet, 30
9231W	<i>Atorvastatin Pfizer, FZ</i> – ATORVASTATIN , atorvastatin 20 mg tablet, 30
9232X	<i>Atorvastatin Pfizer, FZ</i> – ATORVASTATIN , atorvastatin 40 mg tablet, 30
9233Y	<i>Atorvastatin Pfizer, FZ</i> – ATORVASTATIN , atorvastatin 80 mg tablet, 30
8362D	<i>Capecitabine GH, GQ</i> – CAPECITABINE , capecitabine 500 mg tablet, 120
8439E	<i>Kudeq, FZ</i> – CELECOXIB , celecoxib 100 mg capsule, 60
8440F	<i>Kudeq, FZ</i> – CELECOXIB , celecoxib 200 mg capsule, 30
8220P	<i>Citalopram generichealth, GQ</i> – CITALOPRAM , citalopram 20 mg tablet, 28
1397M	<i>Erythrocin-I.V., ZC</i> – ERYTHROMYCIN LACTOBIONATE , erythromycin (as lactobionate) 1 g injection, 1 vial
5088T	<i>Erythrocin-I.V., ZC</i> – ERYTHROMYCIN LACTOBIONATE , erythromycin (as lactobionate) 1 g injection, 1 vial (Dental)
10103R	<i>Exemestane Pfizer, FZ</i> – EXEMESTANE , exemestane 25 mg tablet, 30
8506Q	<i>Exemestane Pfizer, FZ</i> – EXEMESTANE , exemestane 25 mg tablet, 30
1182F	<i>Monopril, BQ</i> – FOSINOPRIL , fosinopril sodium 10 mg tablet, 30
1183G	<i>Monopril, BQ</i> – FOSINOPRIL , fosinopril sodium 20 mg tablet, 30
8401E	<i>Monoplus 20/12.5, BQ</i> – FOSINOPRIL + HYDROCHLOROTHIAZIDE , fosinopril sodium 20 mg + hydrochlorothiazide 12.5 mg tablet, 30
10063P	<i>Isopto Homatropine, AQ</i> – HOMATROPINE , homatropine hydrobromide 2% eye drops, 15 mL (Optometrical)
2541R	<i>Isopto Homatropine, AQ</i> – HOMATROPINE , homatropine hydrobromide 2% eye drops, 15 mL
5552F	<i>Latanoprost Pfizer, FZ</i> – LATANOPROST , latanoprost 0.005% eye drops, 2.5 mL (Optometrical)
8243W	<i>Latanoprost Pfizer, FZ</i> – LATANOPROST , latanoprost 0.005% eye drops, 2.5 mL
5553G	<i>Latanocom, FZ</i> – LATANOPROST + TIMOLOL , latanoprost 0.005% + timolol 0.5% eye drops, 2.5 mL (Optometrical)
8895E	<i>Latanocom, FZ</i> – LATANOPROST + TIMOLOL , latanoprost 0.005% + timolol 0.5% eye drops, 2.5 mL
1316G	<i>Ramipril RBX Tabs, RA</i> – RAMIPRIL , ramipril 10 mg tablet, 30
1945J	<i>Ramipril RBX Tabs, RA</i> – RAMIPRIL , ramipril 2.5 mg tablet, 30
1946K	<i>Ramipril RBX Tabs, RA</i> – RAMIPRIL , ramipril 5 mg tablet, 30

8787L	<i>Risperidone GH, GQ</i> – RISPERIDONE , risperidone 500 microgram tablet, 60
8869T	<i>Risperidone GH, GQ</i> – RISPERIDONE , risperidone 500 microgram tablet, 60
2091C	<i>Microlax, JT</i> – 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
8301X	<i>Altven, FZ</i> – VENLAFAXINE , venlafaxine 75 mg modified release capsule, 28
8302Y	<i>Altven, FZ</i> – VENLAFAXINE , venlafaxine 150 mg modified release capsule, 28
8868R	<i>Altven, FZ</i> – VENLAFAXINE , venlafaxine 37.5 mg modified release capsule, 28

1 January 2017

Deletion – Brand

3408J	<i>Anapen Junior, LM</i> – ADRENALINE , adrenaline 150 microgram/0.3 mL injection, 1 dose
3409K	<i>Anapen, LM</i> – ADRENALINE , adrenaline 300 microgram/0.3 mL injection, 1 dose
8400D	<i>Monoplus 10/12.5, BQ</i> – FOSINOPRIL + HYDROCHLOROTHIAZIDE , fosinopril sodium 10 mg + hydrochlorothiazide 12.5 mg tablet, 30
2712R	<i>Camino Pro Restore, QH</i> – GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS , glycomacropeptide and essential amino acids oral liquid, 12 x 500 mL bottles
2946C	<i>Phosphate Sandoz, NV</i> – PHOSPHORUS , phosphorus 500 mg effervescent tablet, 100
10622C	<i>Hymenoptera Yellow Jacket Venom, DE</i> – VESPUA SPP VENOM , vespuia spp venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial], 1 pack

1 February 2017

Deletion – Brand

8118G	<i>Kalma 2, AF</i> – ALPRAZOLAM , alprazolam 2 mg tablet, 50
8118G	<i>GenRx Alprazolam, GX</i> – ALPRAZOLAM , alprazolam 2 mg tablet, 50
8118G	<i>Alprax 2, QA</i> – ALPRAZOLAM , alprazolam 2 mg tablet, 50
8289G	<i>Avonex, BD</i> – INTERFERON BETA-1A , interferon beta-1a 6 million units (30 microgram) injection [4 vials] (&) inert substance diluent [4 x 1.1 mL syringes], 1 pack
8805K	<i>Avonex, BD</i> – INTERFERON BETA-1A , interferon beta-1a 6 million units (30 microgram)/0.5 mL injection, 4 x 0.5 mL syringes
1574W	<i>Nizoral 2%, JT</i> – KETOCONAZOLE , ketoconazole 2% shampoo, 60 mL
9024Y	<i>Nizoral 2% Cream, JT</i> – KETOCONAZOLE , ketoconazole 2% cream, 30 g
9025B	<i>Nizoral 1%, JT</i> – KETOCONAZOLE , ketoconazole 1% shampoo, 100 mL
9027D	<i>Daktarin, JT</i> – MICONAZOLE , miconazole nitrate 2% cream, 30 g
9028E	<i>Daktarin, JT</i> – MICONAZOLE , miconazole nitrate 2% cream, 70 g
9029F	<i>Daktarin, JT</i> – MICONAZOLE , miconazole nitrate 2% dusting powder, 30 g
9031H	<i>Daktarin Tincture, JT</i> – MICONAZOLE , miconazole 2% solution, 30 mL

Palliative Care

Advance Notices

1 December 2016

Deletion – Brand

5331N	<i>Microlax, JT</i> – 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
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Highly Specialised Drugs Program (Private Hospital)

Additions

Addition – Item

10931H	LIPEGFILGRASTIM , lipegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe (<i>Lonquex</i>)
10923X	RIBAVIRIN , ribavirin 200 mg tablet, 28 (<i>Ibavyr</i>)
10938Q	RIBAVIRIN , ribavirin 200 mg tablet, 28 (<i>Ibavyr</i>)

Deletions

Deletion – Brand

- 6100C Celazadine, JU – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial
6138C Celazadine, JU – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

Alterations

Alteration – Restriction

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

- 6363X **PEGFILGRASTIM**, pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe (*Neulasta*)

Highly Specialised Drugs Program (Public Hospital)

Additions

Addition – Item

- 10936N **LIPEGFILGRASTIM**, lipegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe (*Lonquex*)
10914K **RIBAVIRIN**, ribavirin 200 mg tablet, 28 (*Ibavyr*)
10929F **RIBAVIRIN**, ribavirin 200 mg tablet, 28 (*Ibavyr*)

Deletions

Deletion – Brand

- 9597D Celazadine, JU – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial
9598E Celazadine, JU – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

Alterations

Alteration – Restriction

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

- 9514R **PEGFILGRASTIM**, pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe (*Neulasta*)

Highly Specialised Drugs Program (Community Access)

Alterations

Alteration – Manufacturer Code

- | | | From | To |
|--------|--|------|----|
| 10352W | <i>Foscavir</i> – FOSCARNET , FOSCARNET SODIUM I.V. infusion 24 mg per mL, 250 mL bottle, 6 | IX | LM |

Advance Notices

1 January 2017

Deletion – Brand

- 10350R *Videx EC, BQ* – **DIDANOSINE**, didanosine 125 mg enteric capsule, 30
10351T *Videx EC, BQ* – **DIDANOSINE**, didanosine 200 mg enteric capsule, 30

Growth Hormone Program

Advance Notices

1 January 2017

Deletion – Brand

- 10433D *Saizen 8 mg click.easy*, SG – **SOMATROPIN**, SOMATROPIN (Recombinant human growth hormone) Injection 8 mg (24 i.u.) vial with 1.37 mL diluent cartridge (with preservative) (for use with one.click auto-injector), 1
10471D *Saizen 8 mg click.easy*, SG – **SOMATROPIN**, SOMATROPIN (Recombinant human growth hormone) Injection 8 mg (24 i.u.) vial with 1.37 mL diluent cartridge (with preservative) (for use with one.click auto-injector), 1
6329D *Saizen 8 mg click.easy*, SG – **SOMATROPIN**, SOMATROPIN (Recombinant human growth hormone) Injection 8 mg (24 i.u.) vial with 1.37 mL diluent cartridge (with preservative) (for use with one.click auto-injector), 1

IVF Program

Additions

Addition – Item

10930G **PROGESTERONE**, progesterone 200 mg capsule, 42 (*Utrogestan*)

Repatriation Pharmaceutical Benefits

Deletions

Deletion – Item

4190M **DICLOFENAC + MISOPROSTOL**, diclofenac sodium 50 mg + misoprostol 200 microgram tablet, 60 (*Arthrotec 50*)

Advance Notices

1 December 2016

Deletion – Brand

4755G *Telfa 1970C, KE* – **DRESSING NON ADHERENT**, dressing non adherent 5 cm x 7.5 cm dressing, 10

4758K *Telfa 2140C, KE* – **DRESSING NON ADHERENT**, dressing non adherent 7.5 cm x 10 cm dressing, 6

4844Y *Telfa 7650C, KE* – **DRESSING NON ADHERENT**, dressing non adherent 7.5 cm x 10 cm dressing, 6

General Pharmaceutical Benefits

▪ AFLIBERCEPT

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

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

Note Special Pricing Arrangements apply.

Authority required

Diabetic macular oedema (DMO)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have visual impairment due to diabetic macular oedema, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

- a) a completed authority prescription form;
- b) a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form; and
- c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report. The original documentation must be submitted to the Chief Executive Medicare by post after the application has been authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

Authority required

Diabetic macular oedema (DMO)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by an ophthalmologist.

Note Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

aflibercept 4 mg/0.1 mL injection, 0.1 mL vial

10505X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1148.91	38.30	Eylea [BN]

■ AFLIBERCEPT

Note Special Pricing Arrangements apply.

Authority required

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by an ophthalmologist.
- Authority approval for initial treatment of each eye must be sought.
The first authority application for each eye must be made in writing or by telephone.

A written application must include:

- a) a completed authority prescription form;
- b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form; and
- c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report. The original documentation must be submitted to the Chief Executive Medicare by post after the application has been authorised.

Note The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

Note Authority approvals will be administered by the Complex Drugs Unit of the Department of Human Services.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously been granted an authority prescription for the same eye.

Treatment criteria:

- Must be treated by an ophthalmologist.

Note Authority approvals will be administered by the Complex Drugs Unit of the Department of Human Services.

Note Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Authority required

Central retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by an ophthalmologist.
- Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

- a) a completed authority prescription form;
- b) a completed Central Retinal Vein Occlusion (CRVO) - PBS Supporting Information Form; and
- c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Central Retinal Vein Occlusion (CRVO) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report. The original documentation must be submitted to the Chief Executive Medicare by post after the application has been authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

Note 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

Central retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by an ophthalmologist.

Note Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note 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.

afibercept 4 mg/0.1 mL injection, 0.1 mL vial

2168D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1148.91	38.30	Eylea [BN]

■ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE AND TYROSINE

Restricted benefit

Tyrosinaemia

amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine and tyrosine oral liquid: powder for, 30 x 34 g bottles

10934L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*2952.30	38.30	TYR Easy Shake & Go [OH]

■ ARMODAFINIL

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 This drug is not PBS-subsidised when used in combination with PBS-subsidised dexamphetamine sulphate or modafinil.

Authority required

Narcolepsy

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be for use when therapy with dexamphetamine sulfate poses an unacceptable medical risk; OR
- The treatment must be for use when intolerance to dexamphetamine sulfate is of a severity to necessitate treatment withdrawal, **AND**

- Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months, **AND**
- Patient must have a definite history of cataplexy; OR
- Patient must have a mean sleep latency less than or equal to 10 minutes on a Multiple Sleep Latency Test (MSLT); OR
- Patient must have an electroencephalographic (EEG) recording showing the pathologically rapid development of REM sleep, **AND**
- Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia.

Treatment criteria:

- Must be treated by a qualified sleep medicine practitioner or neurologist.
- The presence of any one of the following indicates treatment with dexamphetamine sulfate poses an unacceptable medical risk:

- (a) a psychiatric disorder;
- (b) a cardiovascular disorder;
- (c) a history of substance abuse;
- (d) glaucoma;
- (e) any other absolute contraindication to dexamphetamine sulfate as specified in the TGA-approved Product Information.

The MSLT must be preceded by nocturnal polysomnography. Sleep prior to the MSLT must be at least 6 hours in duration.

The authority application must be made in writing and must include the following:

- (a) a completed authority prescription form; and
- (b) a completed Narcolepsy Initial PBS authority application and Supporting information form; and
- (c) details of the contraindication or intolerance to dexamphetamine sulfate; and
- (d) either:

- (i) the result and date of the polysomnography test and Multiple Sleep Latency Test (MSLT) conducted by, or under the supervision of, a qualified sleep medicine practitioner; or

- (ii) the result and date of the electroencephalograph (EEG), conducted by, or under the supervision of, a neurologist.

The polysomnography, MSLT or EEG test reports must be provided with the authority application.

Authority required

Narcolepsy

Treatment Phase: Continuing treatment

Clinical criteria:

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

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).

armodafinil 150 mg tablet, 30

10912H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	152.81	38.30	Nuvigil [TB]

armodafinil 250 mg tablet, 30

10919Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	249.64	38.30	Nuvigil [TB]

armodafinil 50 mg tablet, 30

10922W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*105.40	38.30	Nuvigil [TB]

▪ **AURANOFIN**

Caution Regular blood and urine checks are essential.

Note Shared Care Model:

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

auranofin 3 mg tablet, 100

10932J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	392.95	38.30	Ridaura [GH]

▪ **DENOSUMAB**

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Authority required (STREAMLINED)

6548

Osteoporosis

Clinical criteria:

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

Population criteria:

- Patient must be aged 70 years or older.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)**6524**

Established osteoporosis

Clinical criteria:

- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

denosumab 60 mg/mL injection, 1 mL syringe

5457F



Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	..	..	270.96	38.30	Prolia [AN]

■ DEXAMETHASONE

Note Special Pricing Arrangements apply.

Authority required

Diabetic macular oedema (DMO)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have visual impairment due to diabetic macular oedema, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- Patient must have a contraindication to vascular endothelial growth factor (VEGF) inhibitors; OR
- Patient must be unsuitable for treatment with VEGF inhibitors; OR
- Patient must have failed prior treatment with VEGF inhibitors, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Population criteria:

- Patient must have had a cataract removed in the treated eye; OR
- Patient must be scheduled for cataract surgery in the treated eye.

Treatment criteria:

- Must be treated by an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

- a completed authority prescription form;
- a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form; and
- a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report. The original documentation must be submitted to the Chief Executive Medicare by post after the application has been authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

Authority required

Diabetic macular oedema (DMO)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Population criteria:

- Patient must have had a cataract removed in the treated eye; OR
- Patient must be scheduled for cataract surgery in the treated eye.

Treatment criteria:

- Must be treated by an ophthalmologist.

Note Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Diabetic macular oedema (DMO)

Treatment Phase: Grandfathering treatment

Clinical criteria:

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 November 2016, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Population criteria:

- Patient must have had a cataract removed in the treated eye; OR
- Patient must be scheduled for cataract surgery in the treated eye.

Treatment criteria:

- Must be treated by an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

- a completed authority prescription form;
- a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form; and
- a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report. The original documentation must be submitted to the Chief Executive Medicare by post after the application has been authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

dexamethasone 700 microgram implant, 1

10943Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1836.15	38.30	Ozurdex [AG]

▪ **EXENATIDE**

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), an insulin or an SGLT2 inhibitor.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

6519

Diabetes mellitus type 2

Clinical criteria:

- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR
- Patient must not have tolerated a combination of metformin and a sulfonylurea, **AND**

- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with either metformin or a sulfonylurea.

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

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

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

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

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

Authority required (STREAMLINED)

6505

Diabetes mellitus type 2

Clinical criteria:

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea.

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

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

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

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

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

exenatide 2 mg/dose injection: modified release, 4 injection devices

10888C



Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	5	..	130.38	38.30	Bydureon [AP]

■ IMATINIB

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 No applications for increased repeats will be authorised.

Authority required

Malignant gastrointestinal stromal tumour

Treatment Phase: Initial Treatment

Clinical criteria:

- The condition must be metastatic; OR
- The condition must be unresectable, **AND**
- The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining, **AND**
- The treatment must be commenced at a dose not exceeding 400 mg per day, **AND**
- The treatment must not exceed 3 months under this restriction.

Authority prescriptions for a higher dose will not be approved during this initial 3 month treatment period.

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Imatinib Mesilate PBS Authority Application for Use in the Treatment of Metastatic or Unresectable Gastrointestinal Stromal Tumour - Supporting Information Form which includes the following:
 - (i) a copy of a pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining; and
 - (ii) a copy of the most recent (within 2 months of the application) computed tomography (CT) scan, magnetic resonance imaging (MRI) or ultrasound assessment of the tumour(s), including whether or not there is evidence of metastatic disease; and
 - (iii) where the application for authority to prescribe is being sought on the basis of an unresectable tumour, written evidence in support of that claim must be provided

Authority required

Malignant gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be metastatic; OR
- The condition must be unresectable, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given at a dose not exceeding 600 mg per day.

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

Applications for continuing treatment may be made by telephone

Note For the following diseases, written authority is required at initiation and for continuation:

Dermatofibrosarcoma protuberans;
Hypereosinophilic syndrome;
Chronic eosinophilic leukaemia;
Myelodysplastic or myeloproliferative disorder;
Aggressive systemic mastocytosis with eosinophilia.

imatinib 100 mg tablet, 60

9111M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1576.95	38.30	Glivec [AF]

imatinib 400 mg tablet, 30

9112N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3047.02	38.30	Glivec [AF]

■ IMATINIB

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 No applications for increased repeats will be authorised.

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

Authority required

Myelodysplastic or myeloproliferative disorder

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by standard karyotyping; OR

- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by fluorescence in situ hybridization (FISH); OR
 - Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by PDGFRB fusion gene transcript, **AND**
 - Patient must have previously failed an adequate trial of conventional therapy with cytarabine; OR
 - Patient must have previously failed an adequate trial of conventional therapy with etoposide; OR
 - Patient must have previously failed an adequate trial of conventional therapy with hydroxyurea, **AND**
 - The treatment must not exceed a maximum dose of 400 mg per day.
- Applications for authorisation must be made in writing and must include:
- (a) a completed authority prescription form; and
 - (b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
 - (c) a copy of the pathology report confirming the platelet-derived growth factor receptor (PDGFR) gene re-arrangement; and
 - (d) a copy of the bone marrow biopsy report which demonstrates the presence of a myelodysplastic or myeloproliferative disorder; and
 - (e) details of the prior therapy trialled and the response; and
 - (f) a signed patient acknowledgement

Authority required

Myelodysplastic or myeloproliferative disorder

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
 - The condition must be PDGFRB fusion gene-positive, **AND**
 - Patient must have achieved and maintained a complete haematological response, **AND**
 - The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
 - The treatment must not exceed a maximum dose of 400 mg per day.
- Applications for authorisation must be made in writing and must include:
- (a) a completed authority prescription form; and
 - (b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
 - (c) a copy of the full blood examination report which demonstrates a complete haematological response; and
 - (d) a statement that the disease has not progressed on imatinib therapy

imatinib 100 mg capsule, 60

10918P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1576.95	38.30	^a IMATINIB-DRLA [RZ]

imatinib 100 mg tablet, 60

9176Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1576.95	38.30	^a Glivec [AF] ^a Imatinib-Teva [TB]	^a IMATINIB RBX [RA]

imatinib 400 mg capsule, 30

10939R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3047.02	38.30	^a IMATINIB-DRLA [RZ]

imatinib 400 mg tablet, 30

9177B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	3047.02	38.30	^a Glivec [AF] ^a Imatinib-Teva [TB]	^a IMATINIB RBX [RA]

■ IMATINIB

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Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note No applications for increased repeats will be authorised.

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

Authority required

Chronic eosinophilic leukaemia or Hypereosinophilic syndrome

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have confirmed evidence of carrying the FIP1L1-PDGFR fusion gene, **AND**
 - The treatment must not exceed a maximum dose of 400 mg per day.
- Applications for authorisation must be made in writing and must include:
- (a) a completed authority prescription form; and
 - (b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
 - (c) a copy of the pathology report confirming the presence of the FIP1L1-PDGFR fusion gene; and
 - (d) a copy of the full blood examination report confirming the presence of hypereosinophilic syndrome or chronic eosinophilic leukaemia; and
 - (e) details of organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate; and
 - (f) a signed patient acknowledgement

Authority required

Chronic eosinophilic leukaemia or Hypereosinophilic syndrome

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
 - Patient must have achieved and maintained a complete haematological response, **AND**
 - The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
 - The treatment must not exceed a maximum dose of 400 mg per day.
- Applications for authorisation must be made in writing and must include:
- (a) a completed authority prescription form; and
 - (b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
 - (c) a copy of the full blood examination report which demonstrates a complete haematological response, with a normal eosinophil count; and
 - (d) a statement that the disease has not progressed on imatinib therapy

imatinib 100 mg capsule, 60

10941W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1576.95	38.30	^a IMATINIB-DRLA [RZ]

imatinib 100 mg tablet, 60

9174W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1576.95	38.30	^a Glivec [AF] ^a Imatinib-Teva [TB]	^a IMATINIB RBX [RA]

imatinib 400 mg capsule, 30

10925B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3047.02	38.30	^a IMATINIB-DRLA [RZ]

imatinib 400 mg tablet, 30

9175X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	3047.02	38.30	^a Glivec [AF] ^a Imatinib-Teva [TB]	^a IMATINIB RBX [RA]

■ IMATINIB

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Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note No applications for increased repeats will be authorised.

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

Authority required

Dermatofibrosarcoma protuberans

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be unresectable; OR
- The condition must be locally recurrent; OR
- The condition must be metastatic, **AND**

- The treatment must not exceed a maximum dose of 800 mg per day.
- (1) Where the application for authority to prescribe is being sought on the basis of unresectable tumour, written evidence in support of that claim must be provided; and
- (2) Where the application for authority to prescribe is being sought on the basis of locally recurrent disease, the site of the local recurrence must be specified; and
- (3) Where the application for authority to prescribe is being sought on the basis of metastatic disease, the site(s) of metastatic disease must be provided.

Applications for authorisation for initial treatment must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
- (c) a signed patient acknowledgement

Authority required

Dermatofibrosarcoma protuberans

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be unresectable; OR
- The condition must be locally recurrent; OR
- The condition must be metastatic, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to the PBS-subsidised treatment, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 800 mg per day.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
- (c) a statement that the disease has not progressed on imatinib therapy

imatinib 100 mg capsule, 60

10942X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1576.95	38.30	^a IMATINIB-DRLA [RZ]

imatinib 100 mg tablet, 60

9172R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1576.95	38.30	^a Glivec [AF] ^a Imatinib-Teva [TB]	^a IMATINIB RBX [RA]

imatinib 400 mg capsule, 30

10933K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3047.02	38.30	^a IMATINIB-DRLA [RZ]

imatinib 400 mg tablet, 30

9173T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	3047.02	38.30	^a Glivec [AF] ^a Imatinib-Teva [TB]	^a IMATINIB RBX [RA]

■ IMATINIB

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Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

Authority required

Aggressive systemic mastocytosis with eosinophilia

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have confirmed evidence of carrying the FIP1L1-PDGFR fusion gene, **AND**
- Patient must have previously failed an adequate trial of conventional therapy with corticosteroids; OR
- Patient must have previously failed an adequate trial of conventional therapy with hydroxyurea, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
- (c) a copy of the pathology report confirming the presence of the FIP1L1-PDGFRA fusion gene; and
- (d) a copy of the bone marrow biopsy report and/or other tissue biopsy report confirming the diagnosis of aggressive systemic mastocytosis and a copy of the full blood examination report demonstrating eosinophilia; and
- (e) details of symptomatic organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate; and
- (f) details of prior treatment trialled and the response; and
- (g) a signed patient acknowledgement

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

Authority required

Aggressive systemic mastocytosis with eosinophilia

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have confirmed evidence of carrying the FIP1L1-PDGFRA fusion gene, **AND**
- Patient must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
- (c) a copy of the full blood examination report which demonstrates a complete haematological response; and
- (d) a statement that the disease has not progressed on imatinib therapy

Note No applications for increased repeats will be authorised.

imatinib 100 mg capsule, 60

10940T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1576.95	38.30	^a IMATINIB-DRLA [RZ]

imatinib 100 mg tablet, 60

9178C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1576.95	38.30	^a Glivec [AF]	^a IMATINIB RBX [RA]

imatinib 400 mg capsule, 30

10921T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3047.02	38.30	^a IMATINIB-DRLA [RZ]

imatinib 400 mg tablet, 30

9179D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	3047.02	38.30	^a Glivec [AF]	^a IMATINIB RBX [RA]

▪ **IMATINIB**

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Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note No applications for increased repeats will be authorised.

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the accelerated phase, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase.

Accelerated phase is defined by the presence of 1 or more of the following:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or
2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or
3. Peripheral basophils greater than or equal to 20%; or
4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or
5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

Applications for authorisation must be in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Imatinib Mesilate PBS Authority Application for Use in the Treatment of Chronic Myeloid Leukaemia - Supporting Information form, stating which of the above criteria are satisfied by the patient; and
- (c) a copy of the confirming pathology report from an Approved Pathology Authority in the case of criteria (1), (2), (3) and (5) above, or details of the dates of assessments in the case of progressive splenomegaly

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the blast phase, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase.

Blast crisis is defined as either:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or
2. Extramedullary involvement other than spleen and liver.

Applications for authorisation must be in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Imatinib Mesilate PBS Authority Application for Use in the Treatment of Chronic Myeloid Leukaemia - Supporting Information form, stating which of the above criteria are satisfied by the patient; and
- (c) a copy of the confirming pathology report from an Approved Pathology Authority in the case of criterion (1) above, or details of the date of assessment in the case of extramedullary involvement

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be in the accelerated phase, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase.

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be in the blast phase, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase.

imatinib 100 mg capsule, 60

10920R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1576.95	38.30	^a IMATINIB-DRLA [RZ]

imatinib 100 mg tablet, 60

9115R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1576.95	38.30	^a Glivec [AF] ^a Imatinib-Teva [TB]	^a IMATINIB RBX [RA]

imatinib 400 mg capsule, 30

10935M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3047.02	38.30	^a IMATINIB-DRLA [RZ]

imatinib 400 mg tablet, 30

9116T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	3047.02	38.30	^a Glivec [AF] ^a Imatinib-Teva [TB]	^a IMATINIB RBX [RA]

■ IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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 mesilate of 400 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to imatinib mesilate 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 mesilate, 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 mesilate, dasatinib and nilotinib

From 1 April 2012, under the PBS, a patient will be able to be prescribed any of imatinib mesilate, 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 mesilate - 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 mesilate 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 mesilate, 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 mesilate, 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 mesilate, dasatinib or nilotinib:

For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, 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 mesilate, 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 mesilate, 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 mesilate - 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 mesilate 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 mesilate, 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 mesilate, 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 mesilate, dasatinib or nilotinib:

For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, 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 mesilate, 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 mesilate 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 mesilate, 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 mesilate - 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 mesilate 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 mesilate, 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 mesilate, 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 mesilate, dasatinib or nilotinib:

For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, 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 mesilate, 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 capsule, 60

10915L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1576.95	38.30	^a IMATINIB-DRLA [RZ]

imatinib 100 mg tablet, 60

9113P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1576.95	38.30	^a Glivec [AF] ^a Imatinib-Teva [TB]	^a IMATINIB RBX [RA]

imatinib 400 mg capsule, 30

10916M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3047.02	38.30	^a IMATINIB-DRLA [RZ]

imatinib 400 mg tablet, 30

9114Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	3047.02	38.30	^a Glivec [AF] ^a Imatinib-Teva [TB]	^a IMATINIB RBX [RA]

■ IMATINIB

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 Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

Note No applications for increased repeats will be authorised.

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be newly diagnosed, **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 induction and consolidation therapy, **AND**
- The treatment must be in combination with chemotherapy.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Acute Lymphoblastic Leukaemia Imatinib PBS Authority Application - Supporting Information Form; and
- (c) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided); and
- (d) a signed patient acknowledgement

Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase, **AND**
- Patient must have previously received treatment with this drug for this condition under the Imatinib Compassionate Program.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Acute Lymphoblastic Leukaemia Imatinib PBS Authority Application - Supporting Information Form; and
- (c) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided); and
- (d) a signed patient acknowledgement

Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **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 maintenance of first complete remission, **AND**
- The treatment must be in combination with chemotherapy.

Imatinib is available with a lifetime maximum of 24 months for continuing treatment with imatinib therapy for patients with acute lymphoblastic leukaemia reimbursed through the PBS.

Note Any queries concerning the arrangements to prescribe this drug beyond 24 months 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).

imatinib 100 mg capsule, 60

10924Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1576.95	38.30	^a IMATINIB-DRLA [RZ]

imatinib 100 mg tablet, 60

9123E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1576.95	38.30	^a Glivec [AF] ^a Imatinib-Teva [TB]	^a IMATINIB RBX [RA]

imatinib 400 mg capsule, 30

10917N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3047.02	38.30	^a IMATINIB-DRLA [RZ]

imatinib 400 mg tablet, 30

9124F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	3047.02	38.30	^a Glivec [AF] ^a Imatinib-Teva [TB]	^a IMATINIB RBX [RA]

■ MODAFINIL

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 This drug is not PBS-subsidised when used in combination with PBS-subsidised dexamphetamine sulphate or armodafinil.

Authority required

Narcolepsy

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be for use when therapy with dexamphetamine sulfate poses an unacceptable medical risk; OR
- The treatment must be for use when intolerance to dexamphetamine sulfate is of a severity to necessitate treatment withdrawal, **AND**
- Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months, **AND**
- Patient must have a definite history of cataplexy; OR
- Patient must have a mean sleep latency less than or equal to 10 minutes on a Multiple Sleep Latency Test (MSLT); OR
- Patient must have an electroencephalographic (EEG) recording showing the pathologically rapid development of REM sleep, **AND**
- Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia.

Treatment criteria:

- Must be treated by a qualified sleep medicine practitioner or neurologist.
- The presence of any one of the following indicates treatment with dexamphetamine sulfate poses an unacceptable medical risk:

(a) a psychiatric disorder;

(b) a cardiovascular disorder;

(c) a history of substance abuse;

(d) glaucoma;

(e) any other absolute contraindication to dexamphetamine sulfate as specified in the TGA-approved Product Information.

The MSLT must be preceded by nocturnal polysomnography. Sleep prior to the MSLT must be at least 6 hours in duration.

The authority application must be made in writing and must include the following:

(a) a completed authority prescription form; and

(b) a completed Narcolepsy Initial PBS authority application and Supporting information form; and

(c) details of the contraindication or intolerance to dexamphetamine sulfate; and

(d) either:

(i) the result and date of the polysomnography test and Multiple Sleep Latency Test (MSLT) conducted by, or under the supervision of, a qualified sleep medicine practitioner; or

(ii) the result and date of the electroencephalograph (EEG), conducted by, or under the supervision of, a neurologist.

The polysomnography, MSLT or EEG test reports must be provided with the authority application.

Authority required

Narcolepsy

Treatment Phase: Continuing treatment

Clinical criteria:

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

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).

modafinil 100 mg tablet, 60

8816B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*284.70	38.30	^a Modafin [RW]	^a Modavigil [TB]

■ NAFARELIN

Restricted benefit

Endometriosis

Treatment Phase: Initial treatment, for up to 6 months

Clinical criteria:

- The condition must be visually proven.

Restricted benefit

Endometriosis

Treatment Phase: Subsequent treatment, for up to 6 months

Clinical criteria:

- The condition must be visually proven, **AND**
 - The treatment must not be within 2 years of the end of the previous course of treatment with this drug, **AND**
 - Patient must have had a recent bone density assessment.
- The date of the bone density assessment must be recorded in the patient's medical records.

nafarelin 200 microgram/actuation nasal spray, 60 actuations

2962X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	124.53	38.30	Synarel [PF]

■ PHENOXYMETHYLPENICILLIN

phenoxymethylpenicillin 250 mg tablet, 25

1787C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*14.82	16.01	Aspecillin VK [QA]

phenoxymethylpenicillin 250 mg tablet, 25

3360W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	2	..	..	*14.82	16.01	Aspecillin VK [QA]

phenoxymethylpenicillin 500 mg tablet, 25

3028J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*16.86	18.05	Aspecillin VK [QA]

phenoxymethylpenicillin 500 mg tablet, 25

3361X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	2	..	..	*16.86	18.05	Aspecillin VK [QA]

■ PHENOXYMETHYLPENICILLIN

Restricted benefit

Recurrent streptococcal infections (including rheumatic fever)

Clinical criteria:

- The treatment must be for prophylaxis.

phenoxymethylpenicillin 250 mg tablet, 25

1703P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*14.82	16.01	Aspecillin VK [QA]

■ RANIBIZUMAB

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

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

Note Special Pricing Arrangements apply.

Note Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

Authority required

Diabetic macular oedema (DMO)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have visual impairment due to diabetic macular oedema, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

- a completed authority prescription form;
- a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form; and
- a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report.

The original documentation must be submitted to the Chief Executive Medicare by post after the application has been authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

Authority required

Diabetic macular oedema (DMO)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by an ophthalmologist.

Note Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

ranibizumab 1.65 mg/0.165 mL injection, 1 x 0.165 mL syringe

10374B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1148.91	38.30	^a Lucentis [NV]

ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial

10373Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1148.91	38.30	^a Lucentis [NV]

▪ **RANIBIZUMAB**

Note Special Pricing Arrangements apply.

Note Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

Authority required

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

- a) a completed authority prescription form;
- b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form; and
- c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report. The original documentation must be submitted to the Chief Executive Medicare by post after the application has been authorised.

Note The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs

Authority required

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously been granted an authority prescription for the same eye.

Treatment criteria:

- Must be treated by an ophthalmologist.

Note Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Branch retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

- a) a completed authority prescription form;
- b) a completed Branched Retinal Vein Occlusion (BRVO) - PBS Supporting Information Form; and
- c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Branched Retinal Vein Occlusion (BRVO) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report. The original documentation must be submitted to the Chief Executive Medicare by post after the application has been authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

Note 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

Branch retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by an ophthalmologist.

Note Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note 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

Central retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO), **AND**

- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

- a completed authority prescription form;
- a completed Central Retinal Vein Occlusion (CRVO) - PBS Supporting Information Form; and
- a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Central Retinal Vein Occlusion (CRVO) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report. The original documentation must be submitted to the Chief Executive Medicare by post after the application has been authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

Note 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

Central retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by an ophthalmologist.

Note Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note 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.

ranibizumab 1.65 mg/0.165 mL injection, 1 x 0.165 mL syringe

10138N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1148.91	38.30	^a Lucentis [NV]

ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial

1382R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1148.91	38.30	^a Lucentis [NV]

▪ **RIBAVIRIN**

Caution Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

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

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

Population criteria:

- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

ribavirin 200 mg tablet, 28

10928E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	85.82	38.30	Ibavyr [IX]

■ RIBAVIRIN

Caution Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

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

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

Population criteria:

- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

ribavirin 200 mg tablet, 28

10937P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	85.82	38.30	Ibavyr [IX]

■ RUXOLITINIB

Note Risk of myelofibrosis is defined in accordance with the Myelofibrosis International Prognostic Scoring System (IPSS) OR the Dynamic International Prognostic Scoring System (DIPSS) OR the Age-Adjusted DIPSS.

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).

Note No increase in the maximum quantity may be authorised for the 15 mg and 20 mg dose strengths.

Note Special Pricing Arrangements apply.

Authority required

High risk and intermediate-2 risk myelofibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

Authority required

Intermediate-1 risk myelofibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

ruxolitinib 10 mg tablet, 56

10927D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5147.88	38.30	Jakavi [NV]

ruxolitinib 15 mg tablet, 56

10615Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5147.88	38.30	Jakavi [NV]

ruxolitinib 20 mg tablet, 56

10617T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5147.88	38.30	Jakavi [NV]

ruxolitinib 5 mg tablet, 56

10616R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*5147.88	38.30	Jakavi [NV]

■ RUXOLITINIB

Note Risk of myelofibrosis is defined in accordance with the Myelofibrosis International Prognostic Scoring System (IPSS) OR the Dynamic International Prognostic Scoring System (DIPSS) OR the Age-Adjusted DIPSS.

Note Written applications for authority to prescribe should be forwarded to:
Department of Human Services

Complex Programs
Reply Paid 9826
HOBART TAS 7001

Note No increase in the maximum quantity may be authorised for the 15 mg and 20 mg dose strengths.

Note Special Pricing Arrangements apply.

Authority required

High risk and intermediate-2 risk myelofibrosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis.

Note The authority application must be made in writing and must include:

- (1) A completed authority prescription form; and
- (2) A completed Myelofibrosis Authority Application Supporting Information Form, which includes all of the following:
 - (a) A copy of the bone marrow biopsy report confirming diagnosis of myelofibrosis; and
 - (b) A classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS.

Authority required

Intermediate-1 risk myelofibrosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis, **AND**
- Patient must have severe disease-related symptoms that are resistant, refractory or intolerant to available therapy.

Note The authority application must be made in writing and must include:

- (1) A completed authority prescription form; and
- (2) A completed Myelofibrosis Authority Application Supporting Information Form, which includes all of the following:
 - a) A copy of the bone marrow biopsy report confirming diagnosis of myelofibrosis;
 - b) A classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS; and
 - c) A confirmation that the patient's disease related symptoms are resistant, refractory or intolerant to available therapy.

ruxolitinib 10 mg tablet, 56

10913J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	5147.88	38.30	Jakavi [NV]

▪ **USTEKINUMAB**

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy)

Clinical criteria:

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have been receiving treatment with this drug for this condition prior to 1 May 2016, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- Patient must have demonstrated a response to treatment as specified in the criteria for continuing PBS-subsidised treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be an adult.

Treatment criteria:

- Must be treated by a rheumatologist; OR
 - Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.
- For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

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

Note Special Pricing Arrangements apply.

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be an adult.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
- (iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - ustekinumab and secukinumab only.

For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who commenced treatment with secukinumab for psoriatic arthritis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
- (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

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

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

Note Special Pricing Arrangements apply.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial 3 (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) or Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 3 (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority approval for sufficient therapy to complete the balance of supply should be forwarded to:

Department of Human Services
 Complex Drugs
 Reply Paid 9826
 HOBART TAS 7001

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

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

Special Pricing Arrangements apply.

ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial

10767Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	4380.19	38.30	Stelara [JC]

▪ **USTEKINUMAB**

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

- Patient must have severe active psoriatic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be an adult.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

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

Note Special Pricing Arrangements apply.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

Clinical criteria:

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be an adult.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - ustekinumab and secukinumab only.

For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016 and for patients who commenced treatment with secukinumab for psoriatic arthritis prior to 1 October 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response

assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
- (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

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

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

Note Special Pricing Arrangements apply.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more), Initial 2 (change or recommencement of treatment) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of 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 restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority approval for sufficient therapy to complete the balance of supply should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

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

Special Pricing Arrangements apply.

ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial

10774C

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	2	..	4380.19	38.30	Stelara [JC]

Highly Specialised Drugs Program (Private Hospital)

▪ LIPEGFILGRASTIM

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving standard dose adjuvant chemotherapy for breast cancer, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be undergoing induction or consolidation therapy for acute myeloid leukaemia.

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with fludarabine and cyclophosphamide for B-cell chronic lymphocytic leukaemia, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving first-line chemotherapy for Hodgkin disease, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy for myeloma, **AND**
- Patient must have had a prior episode of febrile neutropenia, **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil for inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR

- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia.

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving treatment with aggressive chemotherapy (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide) with the intention of achieving a cure or substantial remission in breast cancer.

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours.

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen).

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease.

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma.

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving treatment with aggressive chemotherapy (first-line chemotherapy with escalated BEACOPP) with the intention of achieving a cure or substantial remission in Hodgkin disease.

lipegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe

10931H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	11	..	1297.02	Lonquex [TB]

▪ **PEGFILGRASTIM**

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving standard dose adjuvant chemotherapy for breast cancer, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be undergoing induction or consolidation therapy for acute myeloid leukaemia.

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with fludarabine and cyclophosphamide for B-cell chronic lymphocytic leukaemia, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR

- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving first-line chemotherapy for Hodgkin disease, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy for myeloma, **AND**
- Patient must have had a prior episode of febrile neutropenia, **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil for inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia.

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving treatment with aggressive chemotherapy (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide) with the intention of achieving a cure or substantial remission in breast cancer.

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours.

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen).

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease.

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma.

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving treatment with aggressive chemotherapy (first-line chemotherapy with escalated BEACOPP) with the intention of achieving a cure or substantial remission in Hodgkin disease.

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in an infant or child with central nervous system tumours.

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma.

pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe

6363X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	11	..	1875.77	Neulasta [AN]

■ RIBAVIRIN

Caution Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

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

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

Population criteria:

- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

ribavirin 200 mg tablet, 28

10923X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	81.02	Ibavyr [IX]

■ RIBAVIRIN

Caution Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

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

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

Population criteria:

- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

ribavirin 200 mg tablet, 28

10938Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	81.02	Ibavyr [IX]

Highly Specialised Drugs Program (Public Hospital)

▪ LIPEGFILGRASTIM

Authority required (STREAMLINED)

6522

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving standard dose adjuvant chemotherapy for breast cancer, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

Authority required (STREAMLINED)

6544

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be undergoing induction or consolidation therapy for acute myeloid leukaemia.

Authority required (STREAMLINED)

6545

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must must be receiving chemotherapy with fludarabine and cyclophosphamide for B-cell chronic lymphocytic leukaemia, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

Authority required (STREAMLINED)

6532

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving first-line chemotherapy for Hodgkin disease, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

Authority required (STREAMLINED)

6515

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy for myeloma, **AND**
- Patient must have had a prior episode of febrile neutropenia, **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

Authority required (STREAMLINED)

6492

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil for inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

Authority required (STREAMLINED)

6507

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia.

Authority required (STREAMLINED)

6533

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving treatment with aggressive chemotherapy (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide) with the intention of achieving a cure or substantial remission in breast cancer.

Authority required (STREAMLINED)

6523

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours.

Authority required (STREAMLINED)

6534

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen).

Authority required (STREAMLINED)

6535

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease.

Authority required (STREAMLINED)

6536

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma.

Authority required (STREAMLINED)

6493

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving treatment with aggressive chemotherapy (first-line chemotherapy with escalated BEACOPP) with the intention of achieving a cure or substantial remission in Hodgkin disease.

lipegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe

10936N

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
1	11	..	1250.00	Lonquex [TB]

▪ **PEGFILGRASTIM**

Authority required (STREAMLINED)

6544

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be undergoing induction or consolidation therapy for acute myeloid leukaemia.

Authority required (STREAMLINED)

6522

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving standard dose adjuvant chemotherapy for breast cancer, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

Authority required (STREAMLINED)

6545

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with fludarabine and cyclophosphamide for B-cell chronic lymphocytic leukaemia, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

Authority required (STREAMLINED)

6532

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving first-line chemotherapy for Hodgkin disease, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

Authority required (STREAMLINED)

6515

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy for myeloma, **AND**
- Patient must have had a prior episode of febrile neutropenia, **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

Authority required (STREAMLINED)

6492

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil for inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

Authority required (STREAMLINED)

6507

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia.

Authority required (STREAMLINED)

6533

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving treatment with aggressive chemotherapy (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide) with the intention of achieving a cure or substantial remission in breast cancer.

Authority required (STREAMLINED)

6523

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours.

Authority required (STREAMLINED)**6534**

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen).

Authority required (STREAMLINED)**6535**

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease.

Authority required (STREAMLINED)**6536**

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma.

Authority required (STREAMLINED)**6493**

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving treatment with aggressive chemotherapy (first-line chemotherapy with escalated BEACOPP) with the intention of achieving a cure or substantial remission in Hodgkin disease.

Authority required (STREAMLINED)**6502**

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in an infant or child with central nervous system tumours.

Authority required (STREAMLINED)**6516**

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma.

pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe

9514R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	11	..	1828.75	Neulasta [AN]

■ RIBAVIRIN

Caution Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

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

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

Population criteria:

- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

ribavirin 200 mg tablet, 28

10914K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	70.00	Ibavyr [IX]

■ RIBAVIRIN

Caution Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

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

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

Population criteria:

- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

ribavirin 200 mg tablet, 28

10929F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	70.00	Ibavyr [IX]

IVF Treatment Program

■ PROGESTERONE

Authority required (STREAMLINED)

4997

Assisted Reproductive Technology

Clinical criteria:

- The treatment must be for luteal phase support as part of an assisted reproductive technology (ART) treatment cycle for infertile women, **AND**
- Patient must be receiving medical services as described in items 13200 or 13201 of the Medicare Benefits Schedule. The luteal phase is defined as the time span from embryo transfer until implantation confirmed by positive B-hCG measurement.

progesterone 200 mg capsule, 42

10930G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	86.55	38.30	Utrogestan [HB]