



Australian Government

Department of Health



Schedule of Pharmaceutical Benefits

Summary of Changes

Effective 1 January 2017



Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 January 2017 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*	\$4.38
Additional Fees (for safety net prices):	Ready-prepared	\$1.19
	Extemporaneously-prepared	\$1.55
Patient Co-payments:	General	\$38.80
	Concessional	\$6.30
Safety Net Thresholds:	General	\$1494.90
	Concessional	\$378.00
Safety Net Card Issue Fee:		\$9.73

* 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 January 2017. The Schedule is updated on the first day of each month and is available on the internet at www.pbs.gov.au.

Prescriber Bag

Alterations

Alteration – Manufacturer Code

		<i>From</i>	<i>To</i>
3472R	Hospira Pty Limited – DEXAMETHASONE SODIUM PHOSPHATE , DEXAMETHASONE SODIUM PHOSPHATE Injection equivalent to 4 mg dexamethasone phosphate in 1 mL, 5	HH	PF
3458B	Hospira Pty Limited – DIAZEPAM , diazepam 10 mg/2 mL injection, 5 x 2 mL ampoules	HH	PF
3479D	Hospira Pty Limited – MORPHINE , morphine sulfate 15 mg/mL injection, 5 x 1 mL ampoules	HH	PF
3480E	Hospira Pty Limited – MORPHINE , morphine sulfate 30 mg/mL injection, 5 x 1 mL ampoules	HH	PF
10786Q	Naloxone Hydrochloride (DBL) – NALOXONE , naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules	HH	PF
3488N	Hospira Pty Limited – PROMETHAZINE , promethazine hydrochloride 50 mg/2 mL injection, 5 x 2 mL ampoules	HH	PF

General Pharmaceutical Benefits

Additions

Addition – Item

10992M	GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS , glycomacropeptide and essential amino acids with vitamins and minerals powder for oral liquid, 30 x 51 g sachets (PKU Bettermilk Lite)
11011M	GRAZOPREVIR + ELBASVIR , grazoprevir 100 mg + elbasvir 50 mg tablet, 28 (Zepatier)
11021C	GRAZOPREVIR + ELBASVIR , grazoprevir 100 mg + elbasvir 50 mg tablet, 28 (Zepatier)

Addition – Brand

8654L	Levetiracetam GH, GQ – LEVETIRACETAM , levetiracetam 250 mg tablet, 60
1207M	EMEXLON, RW – METOCLOPRAMIDE , metoclopramide hydrochloride 10 mg tablet, 25
5151D	EMEXLON, RW – METOCLOPRAMIDE , metoclopramide hydrochloride 10 mg tablet, 25 (Dental)
2190G	PREXUM Combi LD 2.5/0.625, RW – PERINDOPRIL + INDAPAMIDE , perindopril arginine 2.5 mg + indapamide hemihydrate 625 microgram tablet, 30
5232J	Tramadol AMNEAL, EF – TRAMADOL , tramadol hydrochloride 50 mg capsule, 20 (Dental)
8455B	Tramadol AMNEAL, EF – TRAMADOL , tramadol hydrochloride 50 mg capsule, 20
8611F	Tramadol AMNEAL, EF – TRAMADOL , tramadol hydrochloride 50 mg capsule, 20

Addition – Equivalence Indicator

2190G	Coversyl Plus LD 2.5mg/0.625mg, SE – PERINDOPRIL + INDAPAMIDE , perindopril arginine 2.5 mg + indapamide hemihydrate 625 microgram tablet, 30
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Deletions

Deletion – Item

3408J	ADRENALINE , adrenaline 150 microgram/0.3 mL injection, 1 dose (<i>Anapen Junior</i>)
3409K	ADRENALINE , adrenaline 300 microgram/0.3 mL injection, 1 dose (<i>Anapen</i>)
1524F	FLUCLOXACILLIN , flucloxacillin 500 mg injection, 5 vials (<i>Flubiclox</i>)
5094D	FLUCLOXACILLIN , flucloxacillin 500 mg injection, 5 vials (<i>Flubiclox</i>) (Dental)
8400D	FOSINOPRIL + HYDROCHLOROTHIAZIDE , fosinopril sodium 10 mg + hydrochlorothiazide 12.5 mg tablet, 30 (<i>Monoplus 10/12.5</i>)
2712R	GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS , glycomacropeptide and essential amino acids oral liquid, 12 x 500 mL bottles (<i>Camino Pro Restore</i>)
2277W	METRONIDAZOLE , metronidazole 500 mg/100 mL (0.5%) injection, 5 x 100 mL bags (<i>Metronidazole-Claris</i>)
2298Y	METRONIDAZOLE , metronidazole 500 mg/100 mL (0.5%) injection, 5 x 100 mL bags (<i>Metronidazole-Claris</i>) (Dental)
2357C	MILK POWDER LACTOSE MODIFIED PREDIGESTED , milk powder lactose modified predigested powder for oral liquid, 900 g (<i>Digestelact</i>)
2358D	MILK POWDER LACTOSE MODIFIED PREDIGESTED , milk powder lactose modified predigested powder for oral liquid, 900 g (<i>Digestelact</i>)
10620Y	PAPER WASP VENOM , paperwasp venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial], 1 pack (<i>Hymenoptera Paper Wasp Venom</i>)
9197C	PAROXETINE , paroxetine 20 mg tablet, 30 (<i>Paroxetine generichealth</i>)
10622C	VESPULA SPP VENOM , vespula spp venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial], 1 pack (<i>Hymenoptera Yellow Jacket Venom</i>)

Deletion – Brand

1002R	<i>AciVision, DZ</i> – ACICLOVIR , aciclovir 3% eye ointment, 4.5 g
5501M	<i>AciVision, DZ</i> – ACICLOVIR , aciclovir 3% eye ointment, 4.5 g (Optometrical)
1007B	<i>Chem mart Aciclovir, CH</i> – ACICLOVIR , aciclovir 200 mg tablet, 90
1007B	<i>Terry White Chemists Aciclovir, TW</i> – ACICLOVIR , aciclovir 200 mg tablet, 90
8295N	<i>Candesartan RBX, RA</i> – CANDESARTAN , candesartan cilexetil 4 mg tablet, 30
9155W	<i>Deotine 30, SZ</i> – DULOXETINE , duloxetine 30 mg enteric capsule, 28
9156X	<i>Deotine 60, SZ</i> – DULOXETINE , duloxetine 60 mg enteric capsule, 28
1525G	<i>Flubiclox, JU</i> – FLUCLOXACILLIN , flucloxacillin 1 g injection, 5 vials
1525G	<i>Hospira Pty Limited, HH</i> – FLUCLOXACILLIN , flucloxacillin 1 g injection, 5 vials
5095E	<i>Flubiclox, JU</i> – FLUCLOXACILLIN , flucloxacillin 1 g injection, 5 vials (Dental)
5095E	<i>Hospira Pty Limited, HH</i> – FLUCLOXACILLIN , flucloxacillin 1 g injection, 5 vials (Dental)
8654L	<i>Levetiracetam generichealth, GQ</i> – LEVETIRACETAM , levetiracetam 250 mg tablet, 60
1801T	<i>Metformin generichealth, GQ</i> – METFORMIN , metformin hydrochloride 850 mg tablet, 60
3381Y	<i>Olanzapine RBX ODT, RA</i> – OLANZAPINE , OLANZAPINE Tablet 5 mg (orally disintegrating), 28
8185T	<i>Olanzapine GH, GQ</i> – OLANZAPINE , olanzapine 5 mg tablet, 28
8186W	<i>Olanzapine GH, GQ</i> – OLANZAPINE , olanzapine 7.5 mg tablet, 28
3382B	<i>Olanzapine RBX ODT, RA</i> – OLANZAPINE , OLANZAPINE Tablet 10 mg (orally disintegrating), 28
8187X	<i>Olanzapine GH, GQ</i> – OLANZAPINE , olanzapine 10 mg tablet, 28
3384D	<i>Chem mart Olanzapine ODT, CH</i> – OLANZAPINE , olanzapine 15 mg tablet, 28
3384D	<i>Terry White Chemists Olanzapine ODT, TW</i> – OLANZAPINE , olanzapine 15 mg tablet, 28
3385E	<i>Chem mart Olanzapine ODT, CH</i> – OLANZAPINE , olanzapine 20 mg tablet, 28
3385E	<i>Terry White Chemists Olanzapine ODT, TW</i> – OLANZAPINE , olanzapine 20 mg tablet, 28

Deletion – Equivalence Indicator

1821W	<i>Metronidazole Sandoz IV, SZ</i> – METRONIDAZOLE , metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags
1832K	<i>Metronidazole Sandoz IV, SZ</i> – METRONIDAZOLE , metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags (Dental)

Alterations

Alteration – Restriction

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

5481L	CITRULLINE WITH CARBOHYDRATE , citrulline with carbohydrate containing 1 g citrulline oral liquid: powder for, 30 x 4 g sachets (<i>Citrulline 1000</i>)
8180M	INTERFERON ALFA-2A , interferon alfa-2a 3 million units/0.5 mL injection, 0.5 mL syringe (<i>Roferon-A</i>)
8181N	INTERFERON ALFA-2A , interferon alfa-2a 3 million units/0.5 mL injection, 0.5 mL syringe (<i>Roferon-A</i>)
8183Q	INTERFERON ALFA-2A , interferon alfa-2a 6 million units/0.5 mL injection, 0.5 mL syringe (<i>Roferon-A</i>)
8184R	INTERFERON ALFA-2A , interferon alfa-2a 9 million units/0.5 mL injection, 0.5 mL syringe (<i>Roferon-A</i>)
8552D	INTERFERON ALFA-2A , interferon alfa-2a 6 million units/0.5 mL injection, 0.5 mL syringe (<i>Roferon-A</i>)
8553E	INTERFERON ALFA-2A , interferon alfa-2a 9 million units/0.5 mL injection, 0.5 mL syringe (<i>Roferon-A</i>)
8348J	INTERFERON ALFA-2B , interferon alfa-2b 18 million units/1.2 mL injection, 1.2 mL (<i>Intron A Redipen</i>)
8476D	INTERFERON ALFA-2B , interferon alfa-2b 30 million units/1.2 mL injection, 1.2 mL (<i>Intron A Redipen</i>)
8572E	INTERFERON ALFA-2B , interferon alfa-2b 18 million units/1.2 mL injection, 1.2 mL (<i>Intron A Redipen</i>)
1821W	METRONIDAZOLE , metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags (<i>Metronidazole Sandoz IV</i>)
1832K	METRONIDAZOLE , metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags (<i>Metronidazole Sandoz IV</i>)(Dental)
8282X	MILK POWDER LACTOSE FREE FORMULA , milk powder lactose free formula powder for oral liquid, 900 g (<i>S-26 LF</i>)
8283Y	MILK POWDER LACTOSE FREE FORMULA , milk powder lactose free formula powder for oral liquid, 900 g (<i>S-26 LF</i>)
8627C	MONTELUKAST , montelukast 4 mg chewable tablet, 28 (<i>APO-Montelukast, Auro-Montelukast Tabs 4, Chem mart Montelukast, Lukair, Montelukast AN, Montelukast GH, Montelukast Sandoz 4, Respikast 4, Singulair, T Lukast, Terry White Chemists Montelukast</i>)
8628D	MONTELUKAST , montelukast 5 mg chewable tablet, 28 (<i>APO-Montelukast, Auro-Montelukast Tabs 5, Chem mart Montelukast, Lukair, Montelukast AN, Montelukast GH, Montelukast Sandoz 5, Respikast 5, Singulair, T Lukast, Terry White Chemists Montelukast</i>)
9440W	MUPIROICIN , mupirocin 2% (20 mg/g) ointment, 3 g (<i>Bactroban</i>)
2242B	PAROXETINE , paroxetine 20 mg tablet, 30 (<i>Aropax, Chem mart Paroxetine, Extine 20, GenRx Paroxetine, Paroxetine AN, Paroxetine GH, Paroxetine Sandoz, Paxtine, Roxet 20, Terry White Chemists Paroxetine</i>)

Alteration – Manufacturer Code

		From	To
2544X	<i>Akineton</i> – BIPERIDEN , biperiden hydrochloride 2 mg tablet, 100	ZC	GH
1153Q	<i>Neo-Mercazole</i> – CARBIMAZOLE , carbimazole 5 mg tablet, 100	ZC	GH
8315P	<i>DBL Cefepime</i> – CEFEPIME , CEFEPIME Powder for injection 1 g (as hydrochloride), 1	HH	PF
8316Q	<i>DBL Cefepime</i> – CEFEPIME , CEFEPIME Powder for injection 2 g (as hydrochloride), 1	HH	PF
1758M	<i>Hospira Pty Limited</i> – CEFOTAXIME , CEFOTAXIME Powder for injection 1 g, 10	HH	PF
1768C	<i>Hospira Pty Limited</i> – CEFOTAXIME , CEFOTAXIME Powder for injection 1 g, 10 (Dental)	HH	PF
1759N	<i>Hospira Pty Limited</i> – CEFOTAXIME , CEFOTAXIME Powder for injection 2 g, 10	HH	PF
1769D	<i>Hospira Pty Limited</i> – CEFOTAXIME , CEFOTAXIME Powder for injection 2 g, 10 (Dental)	HH	PF
1784X	<i>Hospira Ceftriaxone</i> – CEFTRIAZONE , ceftriaxone 1 g injection, 1 vial	HH	PF
1785Y	<i>Hospira Ceftriaxone</i> – CEFTRIAZONE , ceftriaxone 2 g injection, 1 vial	HH	PF

2964B	<i>Hospira Pty Limited</i> – CEPHALOTHIN , cephalothin 1 g injection, 10 vials	HH	PF
3376Q	<i>Hospira Pty Limited</i> – CEPHALOTHIN , cephalothin 1 g injection, 10 vials (Dental)	HH	PF
1797N	<i>Hospira Cefazolin Sodium</i> – CEPHAZOLIN , cephazolin 1 g injection, 5 vials	HH	PF
1799Q	<i>Hospira Cefazolin Sodium</i> – CEPHAZOLIN , cephazolin 1 g injection, 5 vials	HH	PF
1585K	<i>Hygroton 25</i> – CHLORTHALIDONE , chlorthalidone 25 mg tablet, 50	ZC	GH
9192T	<i>Klacid</i> – CLARITHROMYCIN , clarithromycin 250 mg/5 mL powder for oral liquid, 50 mL	GO	AL
8318T	<i>Klacid</i> – CLARITHROMYCIN , clarithromycin 250 mg tablet, 14	GO	AL
2509C	<i>Hospira Pty Limited</i> – DEXAMETHASONE SODIUM PHOSPHATE , DEXAMETHASONE SODIUM PHOSPHATE Injection equivalent to 4 mg dexamethasone phosphate in 1 mL, 5	HH	PF
1291Y	<i>Hospira Pty Limited</i> – DEXAMETHASONE SODIUM PHOSPHATE , DEXAMETHASONE SODIUM PHOSPHATE Injection equivalent to 8 mg dexamethasone phosphate in 2 mL, 5	HH	PF
2558P	<i>Hospira Pty Limited</i> – DIAZEPAM , diazepam 10 mg/2 mL injection, 5 x 2 mL ampoules	HH	PF
5073B	<i>Hospira Pty Limited</i> – DIAZEPAM , diazepam 10 mg/2 mL injection, 5 x 2 mL ampoules (Dental)	HH	PF
8397Y	<i>Teveten</i> – EPROSARTAN , eprosartan 400 mg tablet, 28	GO	AF
8951D	<i>Teveten</i> – EPROSARTAN , eprosartan 400 mg tablet, 28	GO	AF
5491B	<i>Teveten</i> – EPROSARTAN , eprosartan 600 mg tablet, 28	GO	AF
8447N	<i>Teveten</i> – EPROSARTAN , eprosartan 600 mg tablet, 28	GO	AF
8624X	<i>Teveten Plus 600/12.5</i> – EPROSARTAN + HYDROCHLOROTHIAZIDE , eprosartan 600 mg + hydrochlorothiazide 12.5 mg tablet, 28	GO	AF
2424N	<i>E.E.S. 200</i> – ERYTHROMYCIN ETHYLSUCCINATE , erythromycin (as ethylsuccinate) 200 mg/5 mL powder for oral liquid, 100 mL	ZC	GH
3334L	<i>E.E.S. 200</i> – ERYTHROMYCIN ETHYLSUCCINATE , erythromycin (as ethylsuccinate) 200 mg/5 mL powder for oral liquid, 100 mL (Dental)	ZC	GH
2428T	<i>E.E.S. Granules</i> – ERYTHROMYCIN ETHYLSUCCINATE , erythromycin (as ethylsuccinate) 400 mg/5 mL powder for oral liquid, 100 mL	ZC	GH
3337P	<i>E.E.S. Granules</i> – ERYTHROMYCIN ETHYLSUCCINATE , erythromycin (as ethylsuccinate) 400 mg/5 mL powder for oral liquid, 100 mL (Dental)	ZC	GH
10789W	<i>E.E.S. 400 Filmtab</i> – ERYTHROMYCIN ETHYLSUCCINATE , erythromycin (as ethylsuccinate) 400 mg tablet, 25	ZC	GH
2750R	<i>E.E.S. 400 Filmtab</i> – ERYTHROMYCIN ETHYLSUCCINATE , erythromycin (as ethylsuccinate) 400 mg tablet, 25	ZC	GH
3336N	<i>E.E.S. 400 Filmtab</i> – ERYTHROMYCIN ETHYLSUCCINATE , erythromycin (as ethylsuccinate) 400 mg tablet, 25 (Dental)	ZC	GH
1413J	<i>Zarontin</i> – ETHOSUXIMIDE , ethosuximide 250 mg capsule, 200	PF	IX
1414K	<i>Zarontin</i> – ETHOSUXIMIDE , ethosuximide 250 mg/5 mL oral liquid, 200 mL	PF	IX
9022W	<i>Lipidil</i> – FENOFIBRATE , fenofibrate 48 mg tablet, 60	GO	AF
9246P	<i>Lipidil</i> – FENOFIBRATE , fenofibrate 48 mg tablet, 60	GO	AF
9023X	<i>Lipidil</i> – FENOFIBRATE , fenofibrate 145 mg tablet, 30	GO	AF
9247Q	<i>Lipidil</i> – FENOFIBRATE , fenofibrate 145 mg tablet, 30	GO	AF
10605E	<i>Hospira Pty Limited</i> – FLUCLOXACILLIN , flucloxacillin 1 g injection, 10 vials	HH	PF
10609J	<i>Hospira Pty Limited</i> – FLUCLOXACILLIN , flucloxacillin 1 g injection, 10 vials (Dental)	HH	PF
8512B	<i>Luvox</i> – FLUVOXAMINE , fluvoxamine maleate 50 mg tablet, 30	GO	MQ
8174F	<i>Luvox</i> – FLUVOXAMINE , fluvoxamine maleate 100 mg tablet, 30	GO	MQ
8740B	<i>Leucovorin Calcium (Hospira Pty Limited)</i> – FOLINIC ACID , folinic acid 50 mg/5 mL injection, 5 mL vial	HH	PF
9041W	<i>Leucovorin Calcium (Hospira Pty Limited)</i> – FOLINIC ACID , folinic acid 300 mg/30 mL injection, 30 mL vial	HH	PF
2308L	<i>Leucovorin Calcium (Hospira Pty Limited)</i> – FOLINIC ACID , folinic acid 15 mg tablet, 10	HH	PF

1466E	<i>Hospira Pty Limited</i> – HEPARIN SODIUM , heparin sodium 5000 units/0.2 mL injection, 5 x 0.2 mL ampoules	HH	PF
1076P	<i>Hospira Pty Limited</i> – HEPARIN SODIUM , heparin sodium 35 000 units/35 mL injection, 35 mL vial	HH	PF
9048F	<i>Neo-B12</i> – HYDROXOCOBALAMIN , hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules	HH	PF
3190X	<i>Brufen</i> – IBUPROFEN , ibuprofen 400 mg tablet, 30	GO	AF
3192B	<i>Brufen</i> – IBUPROFEN , ibuprofen 400 mg tablet, 30	GO	AF
5123P	<i>Brufen</i> – IBUPROFEN , ibuprofen 400 mg tablet, 30 (Dental)	GO	AF
5124Q	<i>Brufen</i> – IBUPROFEN , ibuprofen 400 mg tablet, 30 (Dental)	GO	AF
2420J	<i>Tofranil 10</i> – IMIPRAMINE , imipramine hydrochloride 10 mg tablet, 50	ZC	GH
2421K	<i>Tofranil 25</i> – IMIPRAMINE , imipramine hydrochloride 25 mg tablet, 50	ZC	GH
8534E	<i>Zanidip</i> – LERCANIDIPINE , lercanidipine hydrochloride 10 mg tablet, 28	GO	AL
8679T	<i>Zanidip</i> – LERCANIDIPINE , lercanidipine hydrochloride 20 mg tablet, 28	GO	AL
9144G	<i>Zan-Extra 10/10</i> – LERCANIDIPINE + ENALAPRIL , lercanidipine hydrochloride 10 mg + enalapril maleate 10 mg tablet, 28	GO	AF
9145H	<i>Zan-Extra 10/20</i> – LERCANIDIPINE + ENALAPRIL , lercanidipine hydrochloride 10 mg + enalapril maleate 20 mg tablet, 28	GO	AF
2396D	<i>Hospira Pty Limited</i> – METHOTREXATE , methotrexate 5 mg/2 mL injection, 5 x 2 mL vials	HH	PF
2395C	<i>Hospira Pty Limited</i> – METHOTREXATE , methotrexate 50 mg/2 mL injection, 5 x 2 mL vials	HH	PF
1644M	<i>Hospira Pty Limited</i> – MORPHINE , morphine sulfate 10 mg/mL injection, 5 x 1 mL ampoules	HH	PF
5168B	<i>Hospira Pty Limited</i> – MORPHINE , morphine sulfate 10 mg/mL injection, 5 x 1 mL ampoules (Dental)	HH	PF
1645N	<i>Hospira Pty Limited</i> – MORPHINE , morphine sulfate 15 mg/mL injection, 5 x 1 mL ampoules	HH	PF
5169C	<i>Hospira Pty Limited</i> – MORPHINE , morphine sulfate 15 mg/mL injection, 5 x 1 mL ampoules (Dental)	HH	PF
1647Q	<i>Hospira Pty Limited</i> – MORPHINE , morphine sulfate 30 mg/mL injection, 5 x 1 mL ampoules	HH	PF
5170D	<i>Hospira Pty Limited</i> – MORPHINE , morphine sulfate 30 mg/mL injection, 5 x 1 mL ampoules (Dental)	HH	PF
1607N	<i>Hospira Pty Limited</i> – MORPHINE , morphine tartrate 120 mg/1.5 mL injection, 5 x 1.5 mL ampoules	HH	PF
9019Q	<i>Physiotens</i> – MOXONIDINE , moxonidine 200 microgram tablet, 30	GO	AF
9020R	<i>Physiotens</i> – MOXONIDINE , moxonidine 400 microgram tablet, 30	GO	AF
10783M	<i>Naloxone Hydrochloride (DBL)</i> – NALOXONE , naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules	HH	PF
10787R	<i>Naloxone Hydrochloride (DBL)</i> – NALOXONE , naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules (Dental)	HH	PF
8274L	<i>Zumenon</i> – OESTRADIOL , oestradiol 2 mg tablet, 56	GO	AF
10146B	<i>Femoston 1/10</i> – OESTRADIOL (&) OESTRADIOL + DYDROGESTERONE , oestradiol 1 mg tablet [14] (&) oestradiol 1 mg + dydrogesterone 10 mg tablet [14], 1 pack	GO	AF
8244X	<i>Femoston 2/10</i> – OESTRADIOL (&) OESTRADIOL + DYDROGESTERONE , oestradiol 2 mg tablet [14] (&) oestradiol 2 mg + dydrogesterone 10 mg tablet [14], 1 pack	GO	AF
10142T	<i>Femoston-Conti</i> – OESTRADIOL + DYDROGESTERONE , oestradiol 1 mg + dydrogesterone 5 mg tablet, 28	GO	AF
8461H	<i>Pamisol</i> – PAMIDRONATE DISODIUM , pamidronate disodium 15 mg/5 mL injection, 5 mL vial	HH	PF
8462J	<i>Pamisol</i> – PAMIDRONATE DISODIUM , pamidronate disodium 30 mg/10 mL injection, 10 mL vial	HH	PF

8463K	<i>Pamisol</i> – PAMIDRONATE DISODIUM , pamidronate disodium 60 mg/10 mL injection, 10 mL vial	HH	PF
8020D	<i>Creon 10,000</i> – PANCREATIC EXTRACT , pancreatic extract 10 000 units modified release capsule, 100	GO	AF
9226N	<i>Creon 10,000</i> – PANCREATIC EXTRACT , pancreatic extract 10 000 units modified release capsule, 100	GO	AF
8021E	<i>Creon 25,000</i> – PANCREATIC EXTRACT , pancreatic extract 25 000 units modified release capsule, 100	GO	AF
9227P	<i>Creon 25,000</i> – PANCREATIC EXTRACT , pancreatic extract 25 000 units modified release capsule, 100	GO	AF
9412J	<i>Creon 40,000</i> – PANCREATIC EXTRACT , pancreatic extract 40 000 units modified release capsule, 100	GO	AF
9413K	<i>Creon 40,000</i> – PANCREATIC EXTRACT , pancreatic extract 40 000 units modified release capsule, 100	GO	AF
5453B	<i>Creon Micro</i> – PANCREATIC EXTRACT , pancreatic extract 5000 units/100 mg enteric coated granules, 20 g	GO	AF
5454C	<i>Creon Micro</i> – PANCREATIC EXTRACT , pancreatic extract 5000 units/100 mg enteric coated granules, 20 g	GO	AF
1948M	<i>Hospira Pty Limited</i> – PROMETHAZINE , promethazine hydrochloride 50 mg/2 mL injection, 5 x 2 mL ampoules	HH	PF
3374N	<i>Hospira Pty Limited</i> – PROMETHAZINE , promethazine hydrochloride 50 mg/2 mL injection, 5 x 2 mL ampoules (Dental)	HH	PF
1356J	<i>Hospira Pty Limited</i> – TOBRAMYCIN , tobramycin 80 mg/2 mL injection, 5 x 2 mL vials	HH	PF
2791X	<i>Gopten</i> – TRANDOLAPRIL , trandolapril 500 microgram capsule, 28	GO	AL
2792Y	<i>Gopten</i> – TRANDOLAPRIL , trandolapril 1 mg capsule, 28	GO	AL
2793B	<i>Gopten</i> – TRANDOLAPRIL , trandolapril 2 mg capsule, 28	GO	AL
8758Y	<i>Gopten</i> – TRANDOLAPRIL , trandolapril 4 mg capsule, 28	GO	AL
9387C	<i>Tarka 2/180</i> – TRANDOLAPRIL + VERAPAMIL , trandolapril 2 mg + verapamil hydrochloride 180 mg modified release tablet, 28	GO	AF
2857J	<i>Tarka 4/240</i> – TRANDOLAPRIL + VERAPAMIL , trandolapril 4 mg + verapamil hydrochloride 240 mg modified release tablet, 28	GO	AF
3130R	<i>Hospira Pty Limited</i> – VANCOMYCIN , vancomycin 500 mg injection, 1 vial	HH	PF
3131T	<i>Hospira Pty Limited</i> – VANCOMYCIN , vancomycin 500 mg injection, 1 vial	HH	PF
3323X	<i>Hospira Pty Limited</i> – VANCOMYCIN , vancomycin 500 mg injection, 1 vial (Dental)	HH	PF
2269K	<i>Hospira Pty Limited</i> – VANCOMYCIN , vancomycin 1 g injection, 1 vial	HH	PF
2270L	<i>Hospira Pty Limited</i> – VANCOMYCIN , vancomycin 1 g injection, 1 vial	HH	PF
5083M	<i>Hospira Pty Limited</i> – VANCOMYCIN , vancomycin 1 g injection, 1 vial (Dental)	HH	PF
1250T	<i>Isoptin</i> – VERAPAMIL , verapamil hydrochloride 80 mg tablet, 100	GO	MQ
2208F	<i>Cordilox 180 SR</i> – VERAPAMIL , verapamil hydrochloride 180 mg modified release tablet, 30	GT	AL
2208F	<i>Isoptin 180 SR</i> – VERAPAMIL , verapamil hydrochloride 180 mg modified release tablet, 30	GO	MQ
1241H	<i>Cordilox SR</i> – VERAPAMIL , verapamil hydrochloride 240 mg modified release tablet, 30	GT	AL
1241H	<i>Isoptin SR</i> – VERAPAMIL , verapamil hydrochloride 240 mg modified release tablet, 30	GO	MQ
10555M	<i>Ostira</i> – ZOLEDRONIC ACID , zoledronic acid 5 mg/100 mL injection, 100 mL bag	HH	PF
10571J	<i>Ostira</i> – ZOLEDRONIC ACID , zoledronic acid 5 mg/100 mL injection, 100 mL bag	HH	PF

Advance Notices

1 February 2017

Deletion – Brand

8118G	<i>Kalma 2, AF – ALPRAZOLAM</i> , alprazolam 2 mg tablet, 50
8118G	<i>GenRx Alprazolam, GX – ALPRAZOLAM</i> , alprazolam 2 mg tablet, 50
8118G	<i>Alprax 2, QA – ALPRAZOLAM</i> , alprazolam 2 mg tablet, 50
1444B	<i>Krypton 2.5, AF – BROMOCRIPTINE</i> , bromocriptine 2.5 mg tablet, 30
1559C	<i>Krypton 2.5, AF – BROMOCRIPTINE</i> , bromocriptine 2.5 mg tablet, 60
1785Y	<i>Hospira Ceftriaxone, PF – CEFTRIAXONE</i> , ceftriaxone 2 g injection, 1 vial
2655R	<i>Cephalexin generichealth, GQ – CEPHALEXIN</i> , cephalexin 250 mg capsule, 20
3058Y	<i>Cephalexin generichealth, GQ – CEPHALEXIN</i> , cephalexin 250 mg capsule, 20
3317N	<i>Cephalexin generichealth, GQ – CEPHALEXIN</i> , cephalexin 250 mg capsule, 20 (Dental)
3106L	<i>Keto-Diabur- Test 5000, RD – GLUCOSE AND KETONE INDICATOR URINE</i> , glucose and ketone indicator urine diagnostic strip, 50
8289G	<i>Avonex, BD – INTERFERON BETA-1A</i> , interferon beta-1a 6 million units (30 microgram) injection [4 vials] (&) inert substance diluent [4 x 1.1 mL syringes], 1 pack
1801T	<i>Glucophage, MQ – METFORMIN</i> , metformin hydrochloride 850 mg tablet, 60
10634Q	<i>Pegasys RBV, RO – PEGINTERFERON ALFA-2A (&) RIBAVIRIN</i> , peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [168 tablets], 1 pack
10636T	<i>Pegasys RBV, RO – PEGINTERFERON ALFA-2A (&) RIBAVIRIN</i> , peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [140 tablets], 1 pack
3050M	<i>Ozapace, RA – PERINDOPRIL</i> , perindopril erbumine 2 mg tablet, 30
3051N	<i>Ozapace, RA – PERINDOPRIL</i> , perindopril erbumine 4 mg tablet, 30
8704D	<i>Ozapace, RA – PERINDOPRIL</i> , perindopril erbumine 8 mg tablet, 30
8456C	<i>Seronia 25, RF – QUETIAPINE</i> , quetiapine 25 mg tablet, 60
8507R	<i>Prabez, AF – RABEPRAZOLE</i> , rabeprazole sodium 10 mg enteric tablet, 28
8508T	<i>Prabez, AF – RABEPRAZOLE</i> , rabeprazole sodium 20 mg enteric tablet, 30
8509W	<i>Prabez, AF – RABEPRAZOLE</i> , rabeprazole sodium 20 mg enteric tablet, 30
1945J	<i>Prilace 2.5, RW – RAMIPRIL</i> , ramipril 2.5 mg tablet, 30
1946K	<i>Prilace 5, RW – RAMIPRIL</i> , ramipril 5 mg tablet, 30
8470T	<i>Prilace 10, RW – RAMIPRIL</i> , ramipril 10 mg capsule, 30
2055E	<i>Ulcyste, AF – SUCRALFATE</i> , sucralfate 1 g tablet, 120
8144P	<i>Sumagran Aspen 50, RW – SUMATRIPTAN</i> , SUMATRIPTAN Tablet 50 mg (as succinate), 2
5480K	<i>Valnir, OW – VALACICLOVIR</i> , valaciclovir 500 mg tablet, 30
8064K	<i>Valnir, OW – VALACICLOVIR</i> , valaciclovir 500 mg tablet, 42
8133C	<i>Valnir, OW – VALACICLOVIR</i> , valaciclovir 500 mg tablet, 10
8134D	<i>Valnir, OW – VALACICLOVIR</i> , valaciclovir 500 mg tablet, 30

1 April 2017

Deletion – Brand

1788D	<i>Max Pharma Ceftriaxone, GQ – CEFTRIAXONE</i> , CEFTRIAXONE Powder for injection 1 g, 5
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Palliative Care

Alterations

Alteration – Manufacturer Code

5368M	<i>Brufen – IBUPROFEN</i> , ibuprofen 400 mg tablet, 30	From GO	To AF
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Highly Specialised Drugs Program (Private Hospital)

Additions

Addition – Item

10979W	GRAZOPREVIR + ELBASVIR , grazoprevir 100 mg + elbasvir 50 mg tablet, 28 (<i>Zepatier</i>)
10991L	GRAZOPREVIR + ELBASVIR , grazoprevir 100 mg + elbasvir 50 mg tablet, 28 (<i>Zepatier</i>)
11003D	MEPOLIZUMAB , mepolizumab 100 mg injection, 1 vial (<i>Nucala</i>)
11014Q	MEPOLIZUMAB , mepolizumab 100 mg injection, 1 vial (<i>Nucala</i>)
11008J	RIOCIGUAT , riociguat 500 microgram tablet, 84 (<i>Adempas</i>)
11009K	RIOCIGUAT , riociguat 500 microgram tablet, 42 (<i>Adempas</i>)
10990K	RIOCIGUAT , riociguat 1 mg tablet, 42 (<i>Adempas</i>)
11010L	RIOCIGUAT , riociguat 1 mg tablet, 84 (<i>Adempas</i>)
10974N	RIOCIGUAT , riociguat 1.5 mg tablet, 42 (<i>Adempas</i>)
10975P	RIOCIGUAT , riociguat 1.5 mg tablet, 84 (<i>Adempas</i>)
11012N	RIOCIGUAT , riociguat 2 mg tablet, 42 (<i>Adempas</i>)
11017W	RIOCIGUAT , riociguat 2 mg tablet, 84 (<i>Adempas</i>)
10985E	RIOCIGUAT , riociguat 2.5 mg tablet, 42 (<i>Adempas</i>)
11018X	RIOCIGUAT , riociguat 2.5 mg tablet, 84 (<i>Adempas</i>)

Alterations

Alteration – Restriction

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

6221K	AZITHROMYCIN , azithromycin 600 mg tablet, 8 (<i>Zithromax</i>)
6109M	CYCLOSPORIN , cyclosporin 50 mg/mL injection, 10 x 1 mL ampoules (<i>Sandimmun</i>)
6125J	CYCLOSPORIN , cyclosporin 100 mg/mL oral liquid, 50 mL (<i>Neoral</i>)
6232B	CYCLOSPORIN , cyclosporin 10 mg capsule, 60 (<i>Neoral 10</i>)
6352H	CYCLOSPORIN , cyclosporin 25 mg capsule, 30 (<i>Cyclosporin Sandoz, Neoral 25</i>)
6353J	CYCLOSPORIN , cyclosporin 50 mg capsule, 30 (<i>Cyclosporin Sandoz, Neoral 50</i>)
6354K	CYCLOSPORIN , cyclosporin 100 mg capsule, 30 (<i>Cyclosporin Sandoz, Neoral 100</i>)
10182X	ECULIZUMAB , eculizumab 300 mg/30 mL injection, 30 mL vial (<i>Soliris</i>)
10192K	ECULIZUMAB , eculizumab 300 mg/30 mL injection, 30 mL vial (<i>Soliris</i>)
10194M	ECULIZUMAB , eculizumab 300 mg/30 mL injection, 30 mL vial (<i>Soliris</i>)
10521R	ECULIZUMAB , eculizumab 300 mg/30 mL injection, 30 mL vial (<i>Soliris</i>)
1082Y	FILGRASTIM , filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes (<i>TevaGrastim</i>)
1113N	FILGRASTIM , filgrastim 480 microgram/0.8 mL injection, 10 x 0.8 mL syringes (<i>TevaGrastim</i>)
2733W	FILGRASTIM , filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes (<i>Zarzio</i>)
2747N	FILGRASTIM , filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes (<i>Zarzio</i>)
5830W	FILGRASTIM , filgrastim 120 microgram/0.2 mL injection, 10 x 0.2 mL syringes (<i>Nivestim</i>)
6126K	FILGRASTIM , filgrastim 300 microgram/mL injection, 10 x 1 mL vials (<i>Neupogen</i>)
6127L	FILGRASTIM , filgrastim 480 microgram/1.6 mL injection, 10 x 1.6 mL vials (<i>Neupogen</i>)
6291D	FILGRASTIM , filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes (<i>Neupogen</i>)
6292E	FILGRASTIM , filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes (<i>Neupogen</i>)
9693E	FILGRASTIM , filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes (<i>Nivestim</i>)
9695G	FILGRASTIM , filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes (<i>Nivestim</i>)
10184B	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflixtra, Remicade</i>)
6337M	LENOGRASTIM , LENOGRASTIM Powder for injection 13,400,000 i.u. (105 micrograms) vial, 10 (<i>Granocyte 13</i>)
6338N	LENOGRASTIM , LENOGRASTIM Powder for injection 33,600,000 i.u. (263 micrograms) vial, 10 (<i>Granocyte 34</i>)

10110D	OMALIZUMAB , omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe (<i>Xolair</i>)
10122R	OMALIZUMAB , omalizumab 150 mg/mL injection, 1 mL syringe (<i>Xolair</i>)

Alteration – Manufacturer Code

		From	To
10235Q	<i>Apomine</i> – APOMORPHINE , apomorphine hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules	HH	PF
9632Y	<i>Clopine Suspension</i> – CLOZAPINE , clozapine 50 mg/mL oral liquid, 100 mL	HH	PF
6101D	<i>Clopine 25</i> – CLOZAPINE , clozapine 25 mg tablet, 100	HH	PF
6417R	<i>Clopine 50</i> – CLOZAPINE , clozapine 50 mg tablet, 100	HH	PF
6102E	<i>Clopine 100</i> – CLOZAPINE , clozapine 100 mg tablet, 100	HH	PF
6418T	<i>Clopine 200</i> – CLOZAPINE , clozapine 200 mg tablet, 100	HH	PF
6113R	<i>Hospira Pty Limited</i> – DEFERRIOXAMINE , desferrioxamine mesilate 500 mg injection, 10 vials	HH	PF
6270B	<i>Hospira Pty Limited</i> – DEFERRIOXAMINE , desferrioxamine mesilate 2 g injection, 1 vial	HH	PF
5830W	<i>Nivestim</i> – FILGRASTIM , filgrastim 120 microgram/0.2 mL injection, 10 x 0.2 mL syringes	HH	PF
9693E	<i>Nivestim</i> – FILGRASTIM , filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes	HH	PF
9695G	<i>Nivestim</i> – FILGRASTIM , filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes	HH	PF
10057H	<i>Inflectra</i> – INFLIXIMAB , infliximab 100 mg injection, 1 vial	HH	PF
10184B	<i>Inflectra</i> – INFLIXIMAB , infliximab 100 mg injection, 1 vial	HH	PF
6397Q	<i>Inflectra</i> – INFLIXIMAB , infliximab 100 mg injection, 1 vial	HH	PF
6448J	<i>Inflectra</i> – INFLIXIMAB , infliximab 100 mg injection, 1 vial	HH	PF
6496X	<i>Inflectra</i> – INFLIXIMAB , infliximab 100 mg injection, 1 vial	HH	PF
9612X	<i>Inflectra</i> – INFLIXIMAB , infliximab 100 mg injection, 1 vial	HH	PF
9613Y	<i>Inflectra</i> – INFLIXIMAB , infliximab 100 mg injection, 1 vial	HH	PF
9617E	<i>Inflectra</i> – INFLIXIMAB , infliximab 100 mg injection, 1 vial	HH	PF
9674E	<i>Inflectra</i> – INFLIXIMAB , infliximab 100 mg injection, 1 vial	HH	PF
6337M	<i>Granocyte 13</i> – LENOGRASTIM , LENOGRASTIM Powder for injection 13,400,000 i.u. (105 micrograms) vial, 10	HH	PF
6338N	<i>Granocyte 34</i> – LENOGRASTIM , LENOGRASTIM Powder for injection 33,600,000 i.u. (263 micrograms) vial, 10	HH	PF
6227R	<i>Hospira Pty Limited</i> – OCTREOTIDE , octreotide 50 microgram/mL injection, 5 x 1 mL ampoules	HH	PF
6228T	<i>Hospira Pty Limited</i> – OCTREOTIDE , octreotide 100 microgram/mL injection, 5 x 1 mL ampoules	HH	PF
6229W	<i>Hospira Pty Limited</i> – OCTREOTIDE , octreotide 500 microgram/mL injection, 5 x 1 mL ampoules	HH	PF
6286W	<i>Pamisol</i> – PAMIDRONATE DISODIUM , pamidronate disodium 15 mg/5 mL injection, 5 mL vial	HH	PF
6287X	<i>Pamisol</i> – PAMIDRONATE DISODIUM , pamidronate disodium 30 mg/10 mL injection, 10 mL vial	HH	PF
6288Y	<i>Pamisol</i> – PAMIDRONATE DISODIUM , pamidronate disodium 60 mg/10 mL injection, 10 mL vial	HH	PF
6289B	<i>Pamisol</i> – PAMIDRONATE DISODIUM , pamidronate disodium 90 mg/10 mL injection, 10 mL vial	HH	PF
6371H	<i>DBL Zoledronic Acid</i> – ZOLEDRONIC ACID , zoledronic acid 4 mg/5 mL injection, 5 mL vial	HH	PF
10542W	<i>DBL Zoledronic Acid</i> – ZOLEDRONIC ACID , zoledronic acid 4 mg/100 mL injection, 100 mL bag	HH	PF

Advance Notices

1 February 2017

Deletion – Brand

10662E	<i>Pegasys RBV, RO</i> – PEGINTERFERON ALFA-2A (&) RIBAVIRIN , peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes](&) ribavirin 200 mg tablet [168 tablets], 1 pack
10674T	<i>Pegasys RBV, RO</i> – PEGINTERFERON ALFA-2A (&) RIBAVIRIN , peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes](&) ribavirin 200 mg tablet [140 tablets], 1 pack
6392K	<i>Pegasys RBV, RO</i> – PEGINTERFERON ALFA-2A (&) RIBAVIRIN , peginterferon alfa-2a 135 microgram/0.5 mL injection [4 x 0.5 mL syringes](&) ribavirin 200 mg tablet [168 tablets], 1 pack
6394M	<i>Pegasys RBV, RO</i> – PEGINTERFERON ALFA-2A (&) RIBAVIRIN , peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes](&) ribavirin 200 mg tablet [112 tablets], 1 pack
6395N	<i>Pegasys RBV, RO</i> – PEGINTERFERON ALFA-2A (&) RIBAVIRIN , peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes](&) ribavirin 200 mg tablet [140 tablets], 1 pack
6396P	<i>Pegasys RBV, RO</i> – PEGINTERFERON ALFA-2A (&) RIBAVIRIN , peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes](&) ribavirin 200 mg tablet [168 tablets], 1 pack
10197Q	<i>Olysio, JC</i> – SIMEPREVIR , simeprevir sodium 150 mg capsule, 7
6280M	<i>Zelitrex, RF</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 100

Highly Specialised Drugs Program (Public Hospital)

Additions

Addition – Item

10978T	GRAZOPREVIR + ELBASVIR , grazoprevir 100 mg + elbasvir 50 mg tablet, 28 (<i>Zepatier</i>)
10986F	GRAZOPREVIR + ELBASVIR , grazoprevir 100 mg + elbasvir 50 mg tablet, 28 (<i>Zepatier</i>)
10980X	MEPOLIZUMAB , mepolizumab 100 mg injection, 1 vial (<i>Nucala</i>)
10996R	MEPOLIZUMAB , mepolizumab 100 mg injection, 1 vial (<i>Nucala</i>)
10995Q	RIOCIGUAT , riociguat 500 microgram tablet, 84 (<i>Adempas</i>)
11001B	RIOCIGUAT , riociguat 500 microgram tablet, 42 (<i>Adempas</i>)
10976Q	RIOCIGUAT , riociguat 1 mg tablet, 42 (<i>Adempas</i>)
11020B	RIOCIGUAT , riociguat 1 mg tablet, 84 (<i>Adempas</i>)
10977R	RIOCIGUAT , riociguat 1.5 mg tablet, 84 (<i>Adempas</i>)
10989J	RIOCIGUAT , riociguat 1.5 mg tablet, 42 (<i>Adempas</i>)
10984D	RIOCIGUAT , riociguat 2 mg tablet, 42 (<i>Adempas</i>)
11013P	RIOCIGUAT , riociguat 2 mg tablet, 84 (<i>Adempas</i>)
11002C	RIOCIGUAT , riociguat 2.5 mg tablet, 42 (<i>Adempas</i>)
11019Y	RIOCIGUAT , riociguat 2.5 mg tablet, 84 (<i>Adempas</i>)

Alterations

Alteration – Restriction

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

5616N	AZITHROMYCIN , azithromycin 600 mg tablet, 8 (<i>Zithromax</i>)
5631J	CYCLOSPORIN , cyclosporin 50 mg/mL injection, 10 x 1 mL ampoules (<i>Sandimmun</i>)
5632K	CYCLOSPORIN , cyclosporin 10 mg capsule, 60 (<i>Neoral 10</i>)
5633L	CYCLOSPORIN , cyclosporin 100 mg/mL oral liquid, 50 mL (<i>Neoral</i>)
5634M	CYCLOSPORIN , cyclosporin 25 mg capsule, 30 (<i>Cyclosporin Sandoz, Neoral 25</i>)
5635N	CYCLOSPORIN , cyclosporin 50 mg capsule, 30 (<i>Cyclosporin Sandoz, Neoral 50</i>)
5636P	CYCLOSPORIN , cyclosporin 100 mg capsule, 30 (<i>Cyclosporin Sandoz, Neoral 100</i>)
10183Y	ECULIZUMAB , eculizumab 300 mg/30 mL injection, 30 mL vial (<i>Soliris</i>)
10190H	ECULIZUMAB , eculizumab 300 mg/30 mL injection, 30 mL vial (<i>Soliris</i>)
10191J	ECULIZUMAB , eculizumab 300 mg/30 mL injection, 30 mL vial (<i>Soliris</i>)

10525Y	ECULIZUMAB , eculizumab 300 mg/30 mL injection, 30 mL vial (<i>Soliris</i>)
1123D	FILGRASTIM , filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes (<i>TevaGrastim</i>)
1126G	FILGRASTIM , filgrastim 480 microgram/0.8 mL injection, 10 x 0.8 mL syringes (<i>TevaGrastim</i>)
2758E	FILGRASTIM , filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes (<i>Zarzio</i>)
2783L	FILGRASTIM , filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes (<i>Zarzio</i>)
5741E	FILGRASTIM , filgrastim 300 microgram/mL injection, 10 x 1 mL vials (<i>Neupogen</i>)
5742F	FILGRASTIM , filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes (<i>Neupogen</i>)
5743G	FILGRASTIM , filgrastim 480 microgram/1.6 mL injection, 10 x 1.6 mL vials (<i>Neupogen</i>)
5744H	FILGRASTIM , filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes (<i>Neupogen</i>)
5829T	FILGRASTIM , filgrastim 120 microgram/0.2 mL injection, 10 x 0.2 mL syringes (<i>Nivestim</i>)
9692D	FILGRASTIM , filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes (<i>Nivestim</i>)
9694F	FILGRASTIM , filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes (<i>Nivestim</i>)
10196P	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflectra</i> , <i>Remicade</i>)
5787N	LENOGRASTIM , LENOGRASTIM Powder for injection 13,400,000 i.u. (105 micrograms) vial, 10 (<i>Granocyte 13</i>)
5788P	LENOGRASTIM , LENOGRASTIM Powder for injection 33,600,000 i.u. (263 micrograms) vial, 10 (<i>Granocyte 34</i>)
10109C	OMALIZUMAB , omalizumab 150 mg/mL injection, 1 mL syringe (<i>Xolair</i>)
10118M	OMALIZUMAB , omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe (<i>Xolair</i>)

Alteration – Manufacturer Code

		From	To
10227G	<i>Apomine</i> – APOMORPHINE , apomorphine hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules	HH	PF
5630H	<i>Clopine Suspension</i> – CLOZAPINE , clozapine 50 mg/mL oral liquid, 100 mL	HH	PF
5628F	<i>Clopine 25</i> – CLOZAPINE , clozapine 25 mg tablet, 100	HH	PF
5626D	<i>Clopine 50</i> – CLOZAPINE , clozapine 50 mg tablet, 100	HH	PF
5629G	<i>Clopine 100</i> – CLOZAPINE , clozapine 100 mg tablet, 100	HH	PF
5627E	<i>Clopine 200</i> – CLOZAPINE , clozapine 200 mg tablet, 100	HH	PF
5662B	<i>Hospira Pty Limited</i> – DEFERRIOXAMINE , desferrioxamine mesilate 500 mg injection, 10 vials	HH	PF
5661Y	<i>Hospira Pty Limited</i> – DEFERRIOXAMINE , desferrioxamine mesilate 2 g injection, 1 vial	HH	PF
5829T	<i>Nivestim</i> – FILGRASTIM , filgrastim 120 microgram/0.2 mL injection, 10 x 0.2 mL syringes	HH	PF
9692D	<i>Nivestim</i> – FILGRASTIM , filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes	HH	PF
9694F	<i>Nivestim</i> – FILGRASTIM , filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes	HH	PF
10067W	<i>Inflectra</i> – INFLIXIMAB , infliximab 100 mg injection, 1 vial	HH	PF
10196P	<i>Inflectra</i> – INFLIXIMAB , infliximab 100 mg injection, 1 vial	HH	PF
5753T	<i>Inflectra</i> – INFLIXIMAB , infliximab 100 mg injection, 1 vial	HH	PF
5754W	<i>Inflectra</i> – INFLIXIMAB , infliximab 100 mg injection, 1 vial	HH	PF
5755X	<i>Inflectra</i> – INFLIXIMAB , infliximab 100 mg injection, 1 vial	HH	PF
5756Y	<i>Inflectra</i> – INFLIXIMAB , infliximab 100 mg injection, 1 vial	HH	PF
5757B	<i>Inflectra</i> – INFLIXIMAB , infliximab 100 mg injection, 1 vial	HH	PF
5758C	<i>Inflectra</i> – INFLIXIMAB , infliximab 100 mg injection, 1 vial	HH	PF
9654D	<i>Inflectra</i> – INFLIXIMAB , infliximab 100 mg injection, 1 vial	HH	PF
5787N	<i>Granocyte 13</i> – LENOGRASTIM , LENOGRASTIM Powder for injection 13,400,000 i.u. (105 micrograms) vial, 10	HH	PF
5788P	<i>Granocyte 34</i> – LENOGRASTIM , LENOGRASTIM Powder for injection 33,600,000 i.u. (263 micrograms) vial, 10	HH	PF
9508K	<i>Hospira Pty Limited</i> – OCTREOTIDE , octreotide 50 microgram/mL injection, 5 x 1 mL ampoules	HH	PF

9509L	<i>Hospira Pty Limited</i> – OCTREOTIDE , octreotide 100 microgram/mL injection, 5 x 1 mL ampoules	HH	PF
9510M	<i>Hospira Pty Limited</i> – OCTREOTIDE , octreotide 500 microgram/mL injection, 5 x 1 mL ampoules	HH	PF
5667G	<i>Pamisol</i> – PAMIDRONATE DISODIUM , pamidronate disodium 15 mg/5 mL injection, 5 mL vial	HH	PF
5668H	<i>Pamisol</i> – PAMIDRONATE DISODIUM , pamidronate disodium 30 mg/10 mL injection, 10 mL vial	HH	PF
5669J	<i>Pamisol</i> – PAMIDRONATE DISODIUM , pamidronate disodium 60 mg/10 mL injection, 10 mL vial	HH	PF
5670K	<i>Pamisol</i> – PAMIDRONATE DISODIUM , pamidronate disodium 90 mg/10 mL injection, 10 mL vial	HH	PF
9653C	<i>DBL Zoledronic Acid</i> – ZOLEDRONIC ACID , zoledronic acid 4 mg/5 mL injection, 5 mL vial	HH	PF
10561W	<i>DBL Zoledronic Acid</i> – ZOLEDRONIC ACID , zoledronic acid 4 mg/100 mL injection, 100 mL bag	HH	PF

Advance Notices

1 February 2017

Deletion – Brand

10655T	<i>Pegasys RBV, RO</i> – PEGINTERFERON ALFA-2A (&) RIBAVIRIN , peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [168 tablets], 1 pack
10664G	<i>Pegasys RBV, RO</i> – PEGINTERFERON ALFA-2A (&) RIBAVIRIN , peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [140 tablets], 1 pack
9524G	<i>Pegasys RBV, RO</i> – PEGINTERFERON ALFA-2A (&) RIBAVIRIN , peginterferon alfa-2a 135 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [168 tablets], 1 pack
9525H	<i>Pegasys RBV, RO</i> – PEGINTERFERON ALFA-2A (&) RIBAVIRIN , peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [112 tablets], 1 pack
9526J	<i>Pegasys RBV, RO</i> – PEGINTERFERON ALFA-2A (&) RIBAVIRIN , peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [140 tablets], 1 pack
9527K	<i>Pegasys RBV, RO</i> – PEGINTERFERON ALFA-2A (&) RIBAVIRIN , peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [168 tablets], 1 pack
10200W	<i>Olysio, JC</i> – SIMEPREVIR , simeprevir sodium 150 mg capsule, 7
9568N	<i>Zelitrex, RF</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 100

Highly Specialised Drugs Program (Community Access)

Deletions

Deletion – Item

10350R	DIDANOSINE , didanosine 125 mg enteric capsule, 30 (<i>Videx EC</i>)
10351T	DIDANOSINE , didanosine 200 mg enteric capsule, 30 (<i>Videx EC</i>)

Alterations

Alteration – Manufacturer Code

		From	To
10341G	<i>Clopine Suspension</i> – CLOZAPINE , clozapine 50 mg/mL oral liquid, 100 mL	HH	PF
10289M	<i>Clopine 25</i> – CLOZAPINE , clozapine 25 mg tablet, 100	HH	PF
10302F	<i>Clopine 50</i> – CLOZAPINE , clozapine 50 mg tablet, 100	HH	PF
10358E	<i>Clopine 100</i> – CLOZAPINE , clozapine 100 mg tablet, 100	HH	PF
10288L	<i>Clopine 200</i> – CLOZAPINE , clozapine 200 mg tablet, 100	HH	PF

Botulinum Toxin Program

Additions

Addition – Item

10993N	BOTULINUM TOXIN TYPE A , botulinum toxin type A 100 units injection, 1 vial (<i>Botox</i>)
10997T	BOTULINUM TOXIN TYPE A , botulinum toxin type A 100 units injection, 1 vial (<i>Botox</i>)
10998W	BOTULINUM TOXIN TYPE A , botulinum toxin type A 100 units injection, 1 vial (<i>Botox</i>)
10999X	BOTULINUM TOXIN TYPE A , botulinum toxin type A 100 units injection, 1 vial (<i>Botox</i>)
11000Y	BOTULINUM TOXIN TYPE A , botulinum toxin type A 100 units injection, 1 vial (<i>Botox</i>)
11004E	BOTULINUM TOXIN TYPE A , botulinum toxin type A 100 units injection, 1 vial (<i>Botox</i>)
11016T	BOTULINUM TOXIN TYPE A , botulinum toxin type A 100 units injection, 1 vial (<i>Botox</i>)
11023E	BOTULINUM TOXIN TYPE A , botulinum toxin type A 100 units injection, 1 vial (<i>Botox</i>)
10981Y	CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX , clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 vial (<i>Dysport</i>)
10982B	CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX , clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 vial (<i>Dysport</i>)
10987G	CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX , clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 vial (<i>Dysport</i>)
11007H	CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX , clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 vial (<i>Dysport</i>)
10988H	CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX , clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 vial (<i>Dysport</i>)
11006G	CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX , clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 vial (<i>Dysport</i>)
11015R	CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX , clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 vial (<i>Dysport</i>)
11022D	CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX , clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 vial (<i>Dysport</i>)
10983C	INCOBOTULINUMTOXINA , incobotulinumtoxinA 100 mouse LD50 units injection, 1 x 100 mouse LD50 units vial (<i>Xeomin</i>)
10994P	INCOBOTULINUMTOXINA , incobotulinumtoxinA 100 mouse LD50 units injection, 1 x 100 mouse LD50 units vial (<i>Xeomin</i>)
11005F	INCOBOTULINUMTOXINA , incobotulinumtoxinA 100 mouse LD50 units injection, 1 x 100 mouse LD50 units vial (<i>Xeomin</i>)

Deletions

Deletion – Item

6103F	BOTULINUM TOXIN TYPE A , botulinum toxin type A 100 units injection, 1 vial (<i>Botox</i>)
1152P	CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX , clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 vial (<i>Dysport</i>)
6293F	CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX , clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 vial (<i>Dysport</i>)
10253P	INCOBOTULINUMTOXINA , incobotulinumtoxinA 100 mouse LD50 units injection, 1 x 100 mouse LD50 units vial (<i>Xeomin</i>)

Growth Hormone Program

Deletions

Deletion – Item

10433D	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 (<i>Saizen 8 mg click.easy</i>)
10471D	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 (<i>Saizen 8 mg click.easy</i>)
6329D	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 (<i>Saizen 8 mg click.easy</i>)

IVF Program

Deletions

Deletion – Item

9631X **CHORIOGONADOTROPIN ALFA**, choriogonadotropin alfa 250 microgram/0.5 mL injection, 0.5 mL syringe (Ovidrel)

Repatriation Pharmaceutical Benefits

Additions

Addition – Brand

4179Y *Blooms the Chemist Clopidogrel, IB* – **CLOPIDOGREL**, clopidogrel 75 mg tablet, 28
4016J *Clonea 6 Day Cream, AF* – **CLOTRIMAZOLE**, clotrimazole 1% vaginal cream, 35 g
4238C *Pharmacy Action Fexorelief 120, GQ* – **FEXOFENADINE**, fexofenadine hydrochloride 120 mg tablet, 30
4325P *Pharmacy Action Worm Treatment, GQ* – **MEBENDAZOLE**, mebendazole 100 mg tablet, 6

Addition – Equivalence Indicator

4325P *Vermox, IA* – **MEBENDAZOLE**, mebendazole 100 mg tablet, 6

Deletions

Deletion – Item

4396J **TERAZOSIN**, terazosin 1 mg tablet [7 tablets] (&) terazosin 2 mg tablet [7 tablets], 14 (*Hytrin*)
4397K **TERAZOSIN**, terazosin 2 mg tablet, 28 (*Hytrin*)
4398L **TERAZOSIN**, terazosin 5 mg tablet, 28 (*Hytrin*)
4399M **TERAZOSIN**, terazosin 10 mg tablet, 28 (*Hytrin*)

Alterations

Alteration – Manufacturer Code

		From	To
10587F	<i>Neo-B12</i> – HYDROXOCOBALAMIN , hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules	HH	PF

General Pharmaceutical Benefits

■ CITRULLINE WITH CARBOHYDRATE

Note Citrulline with carbohydrate is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism.

Restricted benefit

Urea cycle disorders

Clinical criteria:

- The treatment must be for preventing low plasma arginine levels; OR
- The treatment must be for preventing low citrulline levels.

citrulline with carbohydrate containing 1 g citrulline oral liquid: powder for, 30 x 4 g sachets

5481L



Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4	5	..	*486.02	38.80	Citrulline 1000 [VF]	

■ GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS

Restricted benefit

Phenylketonuria

glycomacropeptide and essential amino acids with vitamins and minerals powder for oral liquid, 30 x 51 g sachets

10992M



Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
4	5	..	*2067.90	38.80	PKU Bettermilk Lite [QH]	

■ GRAZOPREVIR + ELBASVIR

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

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 16 weeks.

grazoprevir 100 mg + elbasvir 50 mg tablet, 28

11011M

Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	3	..	21147.88	38.80	Zepatier [MK]	

■ GRAZOPREVIR + ELBASVIR

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

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.

grazoprevir 100 mg + elbasvir 50 mg tablet, 28

11021C	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1		2	..	21147.88	38.80	Zepatier [MK]

■ INTERFERON ALFA-2A

Caution Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Authority required

Myeloproliferative disease

Clinical criteria:

- Patient must have excessive thrombocytosis.

interferon alfa-2a 6 million units/0.5 mL injection, 0.5 mL syringe

8552D	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5		4	..	*319.22	38.80	Roferon-A [RO]

interferon alfa-2a 9 million units/0.5 mL injection, 0.5 mL syringe

8553E	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5		4	..	*476.72	38.80	Roferon-A [RO]

■ INTERFERON ALFA-2A

Caution Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Authority required

Low grade non-Hodgkin's lymphoma

Clinical criteria:

- The condition must have clinical features suggestive of a poor prognosis, **AND**
- The treatment must be in combination with anthracycline-based chemotherapy.

interferon alfa-2a 3 million units/0.5 mL injection, 0.5 mL syringe

8181N	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	15		5	..	*476.82	38.80	Roferon-A [RO]

interferon alfa-2a 6 million units/0.5 mL injection, 0.5 mL syringe

8183Q	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5		5	..	*319.22	38.80	Roferon-A [RO]

interferon alfa-2a 9 million units/0.5 mL injection, 0.5 mL syringe

8184R	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5		5	..	*476.72	38.80	Roferon-A [RO]

■ INTERFERON ALFA-2A

Caution Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Authority required

Hairy cell leukaemia

Authority required

Myeloproliferative disease

Clinical criteria:

- Patient must have excessive thrombocytosis.

interferon alfa-2a 3 million units/0.5 mL injection, 0.5 mL syringe

8180M	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	15		4	..	*476.82	38.80	Roferon-A [RO]

■ INTERFERON ALFA-2B

Caution Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Authority required

Hairy cell leukaemia

interferon alfa-2b 18 million units/1.2 mL injection, 1.2 mL

8572E	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3		4	..	*571.14	38.80	Intron A Redipen [MK]

■ INTERFERON ALFA-2B

Caution Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Authority required

Multiple myeloma

Treatment Phase: Maintenance treatment

Clinical criteria:

- The condition must be in remission following chemotherapy.

Authority required

Low grade non-Hodgkin's lymphoma

Clinical criteria:

- The condition must have clinical features suggestive of a poor prognosis, **AND**
- The treatment must be in combination with anthracycline-based chemotherapy.

interferon alfa-2b 18 million units/1.2 mL injection, 1.2 mL

8348J	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3		5	..	*571.14	38.80	Intron A Redipen [MK]

interferon alfa-2b 30 million units/1.2 mL injection, 1.2 mL

8476D	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3		5	..	*949.08	38.80	Intron A Redipen [MK]

■ METRONIDAZOLE

Restricted benefit

Acute anaerobic sepsis

Treatment criteria:

- Must be treated in a hospital.

metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags

1832K	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1		..	..	20.28	21.47	Metronidazole Sandoz IV [SZ]

■ METRONIDAZOLE

Restricted benefit

Prophylaxis to prevent infection

Clinical criteria:

- Patient must be undergoing large bowel surgery.

Restricted benefit

Acute anaerobic sepsis

Treatment criteria:

- Must be treated in a hospital.

metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags

1821W	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1		..	..	20.28	21.47	Metronidazole Sandoz IV [SZ]

■ MILK POWDER LACTOSE FREE FORMULA

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

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

Authority required

Chronic lactose intolerance

Clinical criteria:

- The condition must be proven to be lactose intolerance.

Population criteria:

- Patient must be up to the age of 12 months.

Lactose intolerance must have been proven by either:

- (a) relief of symptoms on supervised withdrawal of lactose from the diet for 3 or 4 days and subsequent re-emergence of symptoms on rechallenge with lactose containing formulae or milk or food; or
- (b) not less than 0.5% reducing substance in stool exudate tested with copper sulfate diagnostic compound tablet; or
- (c) hydrogen breath test.

The date of birth of the patient must be included in the authority application.

milk powder lactose free formula powder for oral liquid, 900 g

8283Y	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5		5	..	*102.52	38.80	S-26 LF [AS]

▪ MILK POWDER LACTOSE FREE FORMULA

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

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

Note No more than 1 application per patient will be authorised.

Authority required

Acute lactose intolerance

Population criteria:

- Patient must be up to the age of 12 months.

The date of birth of the patient must be included in the authority application.

milk powder lactose free formula powder for oral liquid, 900 g

8282X	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	..	..	..	*102.52	38.80	S-26 LF [AS]

▪ MONTELUKAST

Note This drug is not PBS-subsidised for use in a child aged 2 to 5 years with moderate to severe asthma. It is not intended as an alternative for a child aged 2 to 5 years who requires a corticosteroid as a preventer medication.

Note This drug is not subsidised in a child aged 2 to 5 years for use in combination with other preventer medications. PBS subsidy for this drug will therefore cease for a child aged 2 to 5 years who requires a preventer medication in addition to this drug.

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

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

Authority required (STREAMLINED)

6666

Asthma

Treatment Phase: First-line prevention

Clinical criteria:

- The condition must be frequent intermittent; OR
- The condition must be mild persistent, **AND**
- The treatment must be the single preventer agent, **AND**
- The treatment must be an alternative to sodium cromoglycate; OR
- The treatment must be an alternative to nedocromil sodium.

Population criteria:

- Patient must be aged 2 to 5 years inclusive.

montelukast 4 mg chewable tablet, 28

8627C	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	..	19.70	20.89	^a APO-Montelukast [TX] ^a Chem mart Montelukast [CH] ^a Montelukast AN[EA] ^a Montelukast Sandoz 4 [SZ] ^a Terry White Chemists Montelukast [TW]	^a Auro-Montelukast Tabs 4 [DO] ^a Lukair [AL] ^a Montelukast GH [GQ] ^a Respikast 4 [RW] ^a T Lukast [AF]
				^B 2.00	21.70	20.89	^a Singulair [MK]	

▪ MONTELUKAST

Note This drug is not PBS-subsidised for use in a patient aged 15 years or older, or for use in addition to a long-acting beta-agonist in any age group, or for use as a single second line preventer, as an alternative to corticosteroids, in a child aged 6 to 14 years with moderate to severe asthma.

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

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

Authority required (STREAMLINED)

6674

Asthma

Treatment Phase: First-line prevention

Clinical criteria:

- The condition must be frequent intermittent; OR
- The condition must be mild persistent, **AND**
- The treatment must be the single preventer agent, **AND**
- The treatment must be an alternative to sodium cromoglycate; OR
- The treatment must be an alternative to nedocromil sodium.

Population criteria:

- Patient must be aged 6 to 14 years inclusive.

Authority required (STREAMLINED)

6684

Asthma

Treatment Phase: Prevention of condition

Clinical criteria:

- The condition must be exercise-induced, **AND**
- The treatment must be as an alternative to adding salmeterol xinafoate; OR
- The treatment must be as an alternative to adding eformoterol fumarate, **AND**
- The condition must be otherwise well controlled while receiving optimal dose inhaled corticosteroid, **AND**
- Patient must require short-acting beta-2 agonist 3 or more times per week for prevention or relief of residual exercise-related symptoms.

Population criteria:

- Patient must be aged 6 to 14 years inclusive.

montelukast 5 mg chewable tablet, 28

8628D	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1		5	..	19.15	20.34	^a APO-Montelukast [TX] ^a Chem mart Montelukast [CH] ^a Montelukast AN [EA] ^a Montelukast Sandoz 5 [SZ] ^a Singulair [MK] ^a T Lukast [AF]	^a Auro-Montelukast Tabs 5 [DO] ^a Lukair [AL] ^a Montelukast GH [GQ] ^a Respikast 5 [RW] ^a Terry White Chemists Montelukast [TW]

■ MUPIROCIN

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

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

Authority required (STREAMLINED)**6647**

Staphylococcus aureus infection

Clinical criteria:

- Patient must have nasal colonisation with the bacteria.

Population criteria:

- Patient must be an Aboriginal or a Torres Strait Islander person.

mupirocin 2% (20 mg/g) ointment, 3 g

9440W	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1		..	..	22.31	23.50	Bactroban [GK]

■ PAROXETINE**Restricted benefit**

Major depressive disorders

Restricted benefit

Obsessive-compulsive disorder

Restricted benefit

Panic disorder

paroxetine 20 mg tablet, 30

2242B	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1		5	..	14.61	15.80	^a Chem mart Paroxetine [CH] ^a GenRx Paroxetine [GX] ^a Paroxetine GH [GQ] ^a Paxtine [AF] ^a Terry White Chemists Paroxetine [TW]	^a Extine 20 [RW] ^a Paroxetine AN [EA] ^a Paroxetine Sandoz [SZ] ^a Roxet 20 [DO]
				^B 3.07	17.68	15.80	^a Aropax [AS]	

Highly Specialised Drugs Program (Private Hospital)

■ AZITHROMYCIN

Authority required

Mycobacterium avium complex infection

Clinical criteria:

- The treatment must be for prophylaxis, **AND**
- Patient must be human immunodeficiency virus (HIV) positive, **AND**
- Patient must have CD4 cell counts of less than 75 per cubic millimetre.

azithromycin 600 mg tablet, 8

6221K	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2		5	..	*122.22	Zithromax [PF]

■ CYCLOSPORIN

Caution Careful monitoring of patients is mandatory.

Authority required

Management of transplant rejection

Clinical criteria:

- The treatment must be used by organ or tissue transplant recipients.

cyclosporin 50 mg/mL injection, 10 x 1 mL ampoules

6109M	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1		..	..	65.12	Sandimmun [NV]

■ CYCLOSPORIN

Caution Careful monitoring of patients is mandatory.

Authority required

Management of transplant rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must have had an organ or tissue transplantation, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Authority required

Severe atopic dermatitis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- The condition must be ineffective to other systemic therapies; OR
- The condition must be inappropriate for other systemic therapies.

Treatment criteria:

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologists.

Authority required

Severe psoriasis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- The condition must be ineffective to other systemic therapies; OR
- The condition must be inappropriate for other systemic therapies, **AND**
- The condition must have caused significant interference with quality of life.

Treatment criteria:

- Must be treated by a dermatologist.

Authority required

Nephrotic syndrome

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must have failed prior treatment with steroids and cytostatic drugs; OR
- Patient must be intolerant to treatment with steroids and cytostatic drugs; OR
- The condition must be considered inappropriate for treatment with steroids and cytostatic drugs, **AND**
- Patient must not have renal impairment.

Treatment criteria:

- Must be treated by a nephrologist.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- The condition must have been ineffective to prior treatment with classical slow -acting anti-rheumatic agents (including methotrexate); OR
- The condition must be considered inappropriate for treatment with slow -acting anti-rheumatic agents (including methotrexate).

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist.

cyclosporin 10 mg capsule, 60

6232B	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2		5	..	*85.42	Neoral 10 [NV]

cyclosporin 100 mg capsule, 30

6354K	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4		5	..	*575.26	^a Cyclosporin Sandoz [SZ]	^a Neoral 100 [NV]

cyclosporin 100 mg/mL oral liquid, 50 mL

6125J	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4		5	..	*1310.18	Neoral [NV]

cyclosporin 25 mg capsule, 30

6352H	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4		5	..	*141.06	^a Cyclosporin Sandoz [SZ]	^a Neoral 25 [NV]

cyclosporin 50 mg capsule, 30

6353J	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4		5	..	*285.90	^a Cyclosporin Sandoz [SZ]	^a Neoral 50 [NV]

■ **ECULIZUMAB**

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for four weeks of treatment, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis). Please consult the approved PI for information about vaccination against meningococcal infection.

Note Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of, but not limited to:

- Active malignancy;
- Active HIV infection;
- Hematopoietic stem cell transplants;
- Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
- Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
- Active autoimmune diseases;

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

Note The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:

- Presenting clinical features, including history, acute treatment and medications;
- Results of testing for genetic mutations (if available);
- Family history of aHUS, especially in first-degree relatives;
- Patient's prior history of episodes of active and progressing TMA caused by aHUS;
- Exclusion of alternative causes of TMA;
- History of renal or other organ transplant (if any);
- Any other matters considered relevant by the prescriber.

In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

Note The Authority application should include the results of screening for genetic mutations known to confer a high risk of developing aHUS. The results of genetic screening should be provided whether or not a high-risk mutation has been identified.

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

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

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have active and progressing thrombotic microangiopathy (TMA) caused by aHUS, **AND**
- Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample taken prior to plasma exchange or infusion; or, if ADAMTS-13 activity was not collected prior to plasma exchange or infusion, patient must have platelet counts of greater than $30 \times 10^9/L$ and a serum creatinine of greater than $150 \mu\text{mol/L}$, **AND**
- Patient must have a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days, **AND**
- Patient must have clinical features of active organ damage or impairment, **AND**
- Patient must not receive more than 4 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

Evidence of active and progressing TMA is defined by the following:

(1) a platelet count of less than $150 \times 10^9/L$; and evidence of two of the following:

- (i) presence of schistocytes on blood film;
 - (ii) low or absent haptoglobin;
 - (iii) lactate dehydrogenase (LDH) above normal range;
- OR

(2) in recipients of a kidney transplant for end-stage kidney disease due to aHUS, a kidney biopsy confirming TMA; **AND**

(3) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:

(a) kidney impairment as demonstrated by one of the following:

- (i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or
- (ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or
- (iii) a sCr of greater than the age-appropriate ULN in paediatric patients; or
- (iv) a renal biopsy consistent with aHUS;

(b) onset of TMA-related neurological impairment;

(c) onset of TMA-related cardiac impairment;

(d) onset of TMA-related gastrointestinal impairment;

(e) onset of TMA-related pulmonary impairment.

Claims of non-renal TMA-related organ damage should be made at the point of application for initial PBS-subsidised eculizumab (where possible), and should be supported by objective clinical measures. The prescriber's cover letter should establish that the observed organ damage is directly linked to active and progressing TMA, particularly when indirect causes such as severe thrombocytopenia, hypertension and acute renal failure are present at the time of the initial organ impairment.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

The authority application must be in writing and must include:

- (1) A completed authority prescription form; and
- (2) A completed aHUS eculizumab Authority Application Supporting Information Form - Initial PBS-subsidised eculizumab treatment; and
- (3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and
- (4) A detailed cover letter from the prescriber; and
- (5) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
- (6) A measurement of body weight at the time of application; and
- (7) The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion; the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the two weeks prior to collection of the ADAMTS-13 assay; and
- (8) In the case that a sample for ADAMTS-13 assay was not collected prior to plasma exchange or infusion, measurement of ADAMTS-13 activity must be taken 1-2 weeks following the last plasma exchange or infusion. The ADAMTS-13 result must be submitted to the Department of Human Services within 27 days of commencement of eculizumab treatment in order for the patient to be considered as eligible for further PBS-subsidised eculizumab treatment, under **Initial treatment 1-balance of supply**; and

- (9) A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days; and
- (10) Evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records. All tests must have been performed within one month of application; and
- (11) For all patients, a recent measurement of eGFR, platelets and two of either LDH, haptoglobin or schistocytes of no more than 1 week old at the time of application.

eculizumab 300 mg/30 mL injection, 30 mL vial

10182X	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5984.52	Soliris [XI]	

■ ECULIZUMAB

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 4 repeats, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis). Please consult the approved PI for information about vaccination against meningococcal infection.

Note Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of, but not limited to:

- Active malignancy;
- Active HIV infection;
- Hematopoietic stem cell transplants;
- Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
- Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
- Active autoimmune diseases;

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

Note The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:

- Presenting clinical features, including history, acute treatment and medications;
- Results of testing for genetic mutations (if available);
- Family history of aHUS, especially in first-degree relatives;
- Patient's prior history of episodes of active and progressing TMA caused by aHUS;
- Exclusion of alternative causes of TMA;
- History of renal or other organ transplant (if any);
- Any other matters considered relevant by the prescriber.

In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

Note The Authority application should include the results of screening for genetic mutations known to confer a high risk of developing aHUS. The results of genetic screening should be provided whether or not a high-risk mutation has been identified.

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

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

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment - Balance of Supply

Clinical criteria:

- Patient must have received PBS-subsidised initial supply of eculizumab for this condition, **AND**
- Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample, **AND**
- Patient must not receive more than 20 weeks supply under this restriction.

Treatment criteria:

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

ADAMTS-13 activity result must have been submitted to the Department of Human Services. In the case that a sample for ADAMTS-13 activity taken prior to plasma exchange or infusion was not available at the time of application for **Initial Treatment**, ADAMTS-13 activity must have been measured 1-2 weeks following the last plasma exchange or infusion, and must have been submitted to the Department of Human Services within 27 days of commencement of eculizumab. The date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of the last, if any, plasma exchange or infusion that was undertaken in the two weeks prior to collection of the ADAMTS-13 assay must also have been provided to Department of Human Services.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

eculizumab 300 mg/30 mL injection, 30 mL vial

10192K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	4	..	5984.52	Soliris [XI]

■ ECULIZUMAB

- Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 6 repeats, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.
- Note** For patients who have received continuing treatment with PBS-subsidised eculizumab prior to 1 January 2016, this restriction is limited to 28 weeks of therapy.
- Note** **WARNING:** Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis). Please consult the approved PI for information about vaccination against meningococcal infection.
- Note** Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of, but not limited to:
- a) Active malignancy;
 - b) Active HIV infection;
 - c) Hematopoietic stem cell transplants;
 - d) Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
 - e) Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
 - f) Active autoimmune diseases;
- In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.
- Note** The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:
- a) Presenting clinical features, including history, acute treatment and medications;
 - b) Results of testing for genetic mutations (if available);
 - c) Family history of aHUS, especially in first-degree relatives;
 - d) Patient's prior history of episodes of active and progressing TMA caused by aHUS;
 - e) Exclusion of alternative causes of TMA;
 - f) History of renal or other organ transplant (if any);
 - g) Any other matters considered relevant by the prescriber.
- In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.
- Note** The Authority application should include the results of screening for genetic mutations known to confer a high risk of developing aHUS. The results of genetic screening should be provided whether or not a high-risk mutation has been identified.
- Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au. Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Extended initial treatment - Assessment phase

Clinical criteria:

- Patient must have received treatment under the initial restriction with PBS subsidised eculizumab for this condition, **AND**
- Patient must have demonstrated on-going treatment response of PBS-subsidised eculizumab treatment for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must not receive more than 56 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

- (1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; **AND**
 - (2) One of the following:
 - a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or
 - b) an eGFR within +/- 25% from baseline; or
 - c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.
- PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure.

A treatment failure is defined as a patient who is:

- (1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or
- (2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

A maximum of up to 56 weeks of treatment is allowed under this restriction, however an application must be submitted at 6 months, 12 months, 18 months and 24 months following commencing PBS-subsidised eculizumab.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

- (1) A completed authority prescription form; and
- (2) A completed aHUS eculizumab Authority Application Supporting Information Form for Extended Initial treatment; and
- (3) A detailed cover letter from the prescriber; and
- (4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
- (5) A measurement of body weight at the time of application; and
- (6) An identified genetic mutation, if applicable; and
- (7) A family history of aHUS, if applicable; and
- (8) A history of multiple episodes of aHUS before commencing eculizumab treatment, if applicable; and
- (9) A history of kidney transplant, if applicable, (especially if required due to aHUS); and
- (10) An inclusion of the individual consequences of recurrent disease, if applicable; and
- (11) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and
- (12) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
- (13) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

eculizumab 300 mg/30 mL injection, 30 mL vial

10521R	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1		6	..	5984.52	Soliris [X]

■ ECULIZUMAB

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis). Please consult the approved PI for information about vaccination against meningococcal infection.

Note Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of, but not limited to:

- a) Active malignancy;
- b) Active HIV infection;
- c) Hematopoietic stem cell transplants;
- d) Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
- e) Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
- f) Active autoimmune diseases;

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

Note The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:

- a) Presenting clinical features, including history, acute treatment and medications;
- b) Results of testing for genetic mutations (if available);
- c) Family history of aHUS, especially in first-degree relatives;
- d) Patient's prior history of episodes of active and progressing TMA caused by aHUS;
- e) Exclusion of alternative causes of TMA;
- f) History of renal or other organ transplant (if any);
- g) Any other matters considered relevant by the prescriber.

In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

Note The Authority application should include the results of screening for genetic mutations known to confer a high risk of developing aHUS. The results of genetic screening should be provided whether or not a high-risk mutation has been identified.

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

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

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received treatment under Extended Initial restriction with PBS subsidised eculizumab for this condition, **AND**
- Patient must have demonstrated on-going treatment response of PBS-subsidised eculizumab treatment for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; **AND**

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure.

A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

(1) A completed authority prescription form; and

(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and

(3) A detailed cover letter from the prescriber; and

(4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and

(5) A measurement of body weight at the time of application; and

(6) An identified genetic mutation, if applicable; and

(7) A family history of aHUS, if applicable; and

(8) A history of multiple episodes of aHUS before recommencing eculizumab treatment, if applicable; and

(9) A history of kidney transplant if applicable (especially if required due to aHUS); and

(10) An inclusion of the individual consequences of recurrent disease, if applicable; and

(11) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and

(12) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and

(13) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Extended Continuing treatment

Clinical criteria:

- Patient must have received treatment under the Continuing treatment with PBS-subsidised eculizumab for this condition, **AND**
- Patient must have demonstrated on-going treatment response with PBS-subsidised eculizumab for this condition, **AND**
- Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must have a TMA-related cardiomyopathy as evidenced by left ventricular ejection fraction < 40% on current objective measurement; OR
- Patient must have severe TMA-related neurological impairment; OR
- Patient must have severe TMA-related gastrointestinal impairment; OR
- Patient must have severe TMA-related pulmonary impairment on current objective measurement; OR
- Patient must have grade 4 or 5 chronic kidney disease (eGFR of less than 30 mL/min); OR

- Patient must have a high risk of aHUS recurrence in the short term in the absence of continued treatment with eculizumab, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Treatment criteria:

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

- (1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; **AND**
- (2) One of the following:
 - a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or
 - b) an eGFR within +/- 25% from baseline; or
 - c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

- (1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or
- (2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

- (1) A completed authority prescription form; and
- (2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and
- (3) A detailed cover letter from the prescriber; and
- (4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
- (5) A measurement of body weight at the time of application; and
- (6) An identified genetic mutation, if applicable; and
- (7) A family history of aHUS, if applicable; and
- (8) A history of multiple episodes of aHUS before commencing eculizumab treatment, if applicable; and
- (9) A history of kidney transplant, if applicable (especially if required due to aHUS); and
- (10) An inclusion of the individual consequences of recurrent disease; and
- (11) A supporting statement with clinical evidence of severe TMA-related cardiomyopathy (including current LVEF result), neurological impairment, gastrointestinal impairment or pulmonary impairment; and
- (12) Evidence that the patient has had a treatment response including haematological results of no more than 1 month old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 month old at the time of application; and
- (13) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
- (14) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

Note All applications should be accompanied by a detailed letter that outlines the objective evidence of high risk of critical organ damage if aHUS recurs. The following evidence may be submitted to establish the patient's level of risk of aHUS recurrence in the short term in the absence of continued treatment with eculizumab:

- a) Evidence of a mutation known to confer a high risk of aHUS recurrence;
- b) Past history of recurrent episodes of active and progressive TMA due to aHUS, prior to the episode that led to current use of eculizumab;
- c) Past family history of aHUS recurrence, especially in first-degree relatives;
- d) Past history of recurrent aHUS following renal transplant for end-stage renal failure due to aHUS.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Recommencement of treatment

Clinical criteria:

- Patient must have demonstrated treatment response to previous treatment with PBS-subsidised eculizumab for this condition, **AND**
- Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must have the following clinical conditions: (i) either significant haemolysis as measured by low/absent haptoglobin; or presence of schistocytes on the blood film; or lactate dehydrogenase (LDH) above normal; **AND** (ii) either platelet consumption as measured by either 25% decline from patient baseline or thrombocytopenia (platelet count <150 x 10⁹/L); **OR** (iii) TMA-related organ impairment including on recent biopsy, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

(1) A completed authority prescription form(s); and

(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Recommencement of treatment; and

(3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and

(4) A detailed cover letter from the prescriber; and

(5) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and

(6) A measurement of body weight at the time of application, and

(7) An identified genetic mutation, if applicable; and

(8) A family history of aHUS if applicable; and

(9) A history of multiple episodes of aHUS following the treatment break, if applicable; and

(10) A history of kidney transplant if applicable (especially if required due to aHUS); and

(11) An inclusion of the individual consequences of recurrent disease; and

(12) A supporting statement with clinical evidence of TMA-related organ damage including current (within one week of application) haematological results (platelet count, haptoglobin and LDH), eGFR level, and, if applicable, on recent biopsy;

(13) Evidence that the patient has had a treatment response to their previous treatment with eculizumab; and

(14) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and

(15) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

Note A raise in LDH alone is not a sufficient reason to re-commence eculizumab, but thrombocytopenia with one marker of haemolysis (such as raised LDH, presence of schistocytes, or low/absence of haptoglobin) is an accepted reason to consider re-commencement of eculizumab treatment.

Note Kidney transplantation/dialysis is not a contraindication to recommencement of eculizumab treatment.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing recommencement of treatment

Clinical criteria:

- Patient must have received treatment under Recommencement of treatment restriction with PBS-subsidised eculizumab for this condition, **AND**
- Patient must have demonstrated ongoing treatment response to the previous 24 weeks of PBS-subsidised eculizumab for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline. PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

- (1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or
- (2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

- (1) A completed authority prescription form; and
- (2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and
- (3) A detailed cover letter from the prescriber; and
- (4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
- (5) A measurement of body weight at the time of application; and
- (6) An identified genetic mutation, if applicable; and
- (7) A family history of aHUS, if applicable; and
- (8) A history of multiple episodes of aHUS before recommencing eculizumab treatment, if applicable; and
- (9) A history of kidney transplant if applicable (especially if required due to aHUS); and
- (10) An inclusion of the individual consequences of recurrent disease, if applicable; and
- (11) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and
- (12) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
- (13) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

eculizumab 300 mg/30 mL injection, 30 mL vial

10194M	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1		5	..	5984.52	Soliris [XI]

■ FILGRASTIM

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.

Authority required

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

Authority required

Severe congenital neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, **AND**
- Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

Authority required

Severe chronic neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; OR
- Patient must have neutrophil dysfunction, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

Authority required

Chronic cyclical neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

Authority required

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

Authority required

Assisting bone marrow transplantation

Clinical criteria:

- Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

Authority required

Assisting autologous peripheral blood progenitor cell transplantation

Clinical criteria:

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes

1082Y	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2		11	..	*1205.46	TevaGrastim [TB]

▪ **FILGRASTIM**

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 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 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.

Authority required

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

Authority required

Severe congenital neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, **AND**
- Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

Authority required

Severe chronic neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; OR
- Patient must have neutrophil dysfunction, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

Authority required

Chronic cyclical neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

Authority required

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

Authority required

Assisting bone marrow transplantation

Clinical criteria:

- Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

Authority required

Assisting autologous peripheral blood progenitor cell transplantation

Clinical criteria:

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes

6291D	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2		11	..	*1205.46	Neupogen [AN]

filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes

9693E	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2		11	..	*1205.46	Nivestim [PF]

filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes

2747N	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4		11	..	*1205.46	Zarzio [SZ]

filgrastim 300 microgram/mL injection, 10 x 1 mL vials

6126K	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2		11	..	*1205.46	Neupogen [AN]

filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes

6292E	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2		11	..	*1904.08	Neupogen [AN]

filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes

9695G	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2		11	..	*1904.08	Nivestim [PF]

filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes

2733W	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4		11	..	*1904.06	Zarzio [SZ]

filgrastim 480 microgram/0.8 mL injection, 10 x 0.8 mL syringes

1113N	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2		11	..	*1904.08	TevaGrastim [TB]

filgrastim 480 microgram/1.6 mL injection, 10 x 1.6 mL vials

6127L	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2		11	..	*1904.08	Neupogen [AN]

■ FILGRASTIM**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 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 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.

Authority required

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

Authority required

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

Authority required

Assisting bone marrow transplantation

Clinical criteria:

- Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

Authority required

Assisting autologous peripheral blood progenitor cell transplantation

Clinical criteria:

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

Authority required

Severe congenital neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, **AND**
- Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

Authority required

Severe chronic neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; OR
- Patient must have neutrophil dysfunction, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

Authority required

Chronic cyclical neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

filgrastim 120 microgram/0.2 mL injection, 10 x 0.2 mL syringes

Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
5830W	2	11	..	*488.94	Nivestim [PF]

■ **GRAZOPREVIR + ELBASVIR**

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

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.

grazoprevir 100 mg + elbasvir 50 mg tablet, 28

Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
10979W	1	2	..	21047.02	Zepatier [MK]

■ **GRAZOPREVIR + ELBASVIR**

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

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 16 weeks.

grazoprevir 100 mg + elbasvir 50 mg tablet, 28

10991L	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1		3	..	21047.02	Zepatier [MK]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of infliximab, vedolizumab and adalimumab for adult patients with ulcerative colitis. Patients are eligible for PBS-subsidised treatment with either infliximab, vedolizumab or adalimumab at any one time. From 1 December 2016, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial each of PBS-subsidised infliximab, vedolizumab or adalimumab without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with infliximab, vedolizumab or adalimumab while they continue to show a response to therapy. A patient who received PBS-subsidised infliximab, vedolizumab or adalimumab treatment prior to 1 December 2016 is considered to be in their first cycle as of 1 December 2016. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised infliximab, vedolizumab or adalimumab more than once. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised infliximab, vedolizumab or adalimumab treatment in the most recent cycle to the date of the first application for initial treatment with infliximab, vedolizumab or adalimumab under the new treatment cycle. A patient who has failed fewer than 3 trials of either infliximab, vedolizumab or adalimumab in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

(1) How to prescribe PBS-subsidised treatment with infliximab, vedolizumab and adalimumab after therapy after 1 December 2016.

(a) Initial treatment. Applications for initial treatment should be made where:

- an adult patient has received no prior PBS-subsidised treatment with infliximab, vedolizumab or adalimumab in this treatment cycle and wishes to commence such therapy (Initial 1); or
- an adult patient has received prior PBS-subsidised (initial or continuing) infliximab, vedolizumab or adalimumab therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- an adult patient wishes to re-commence treatment with infliximab, vedolizumab or adalimumab following a break in PBS-subsidised therapy with the same agent (Initial 2).

Treatment authorisations under Initial 1 and Initial 2 will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab and vedolizumab.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab, and this assessment must be provided to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist. For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is provided to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with infliximab, vedolizumab or adalimumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment. Assessments of response to a course of PBS-subsidised therapy must be provided to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised treatment is approved, a patient may swap if eligible to the alternate infliximab, vedolizumab or adalimumab treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy. A patient may trial an alternate treatment at any time, regardless of whether they are receiving therapy (initial or continuing) with infliximab, vedolizumab or adalimumab at the time of the application. However, they cannot swap to a particular therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to the alternate infliximab, vedolizumab or adalimumab therapy should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Mayo clinic score or partial Mayo clinic score submitted with the first authority application for infliximab, vedolizumab or adalimumab. However, prescribers may provide new baseline measurements any time other than when an initial treatment authority application is provided within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial

treatment application must be provided for all subsequent continuing treatment applications.

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

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised infliximab, vedolizumab or adalimumab therapy of at least 5 years, must requalify for initial treatment with respect to the scores of disease severity. A patient must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for induction of remission for a minimum of 3 consecutive months, and, either azathioprine or 6-mercaptopurine for a minimum of 3 consecutive months or a tapered course of oral steroids over a 6 week period followed by an appropriately dosed thiopurine agent for a minimum of 3 consecutive months (unless intolerance develops necessitating permanent treatment withdrawal to these agents) immediately prior to the time the Mayo score is measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for moderate to severe ulcerative colitis prior to 1 December 2016 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 3 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

Note Special Pricing Arrangements apply.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment (new patient or Re commencement of treatment after more than 5 years break in therapy - Initial 1)

Clinical criteria:

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years; OR
- Patient must have previously received induction therapy with this drug for an acute severe episode of ulcerative colitis in the last 4 months and demonstrated an adequate response to induction therapy by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a PUCAI score less than 10 (if aged 6 to 17 years).

Population criteria:

- Patient must be 6 years of age or older.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

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

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the signed patient acknowledgement or guardian acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, or to be administered at 8-weekly intervals for patients who have received prior treatment for an acute severe episode, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 1 month old at the time of application.

Where treatment for an acute severe episode has occurred, an adequate response to induction therapy needs to be demonstrated by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than

1, or a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 (if aged 6 to 17 years), within the first 12 weeks of receiving this drug for acute severe ulcerative colitis.

Patients who fail to achieve a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 within the first 12 weeks of receiving this drug for ulcerative colitis, or have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or have failed to maintain a PUCAI score less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose for patients administered doses at weeks 0, 2 and 6 (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The patient or guardian (required if patient is aged 6 to 17 years) must have signed a patient acknowledgement indicating that he or she understands and acknowledges that the PBS-subsidised treatment will cease if he or she does not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

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

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 while receiving treatment with this drug, if aged 6 to 17 years.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

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

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

Up to a maximum of 2 repeats will be authorised.

Note No applications for increased repeats will be authorised.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Change or Re-commencement of treatment after a break in therapy (Initial 2)

Clinical criteria:

- Patient must have previously been issued with an authority prescription for adalimumab, infliximab or vedolizumab for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of this drug within the timelines specified in the relevant restriction. If the response assessment to the previous course of this drug is not submitted as detailed in the relevant restriction, the patient will be deemed to have failed therapy with this drug.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

Up to a maximum of 2 repeats will be authorised.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.

Note No applications for increased repeats will be authorised.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (Change or Recommencement of treatment after a break in therapy) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 3 doses (Initial 1 and Initial 2 restrictions) or 2 repeats (Continuing restriction).

Population criteria:

- Patient must be 6 years of age or older.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.

infliximab 100 mg injection, 1 vial

10184B	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..		604.86	^a Inflectra [PF]	^a Remicade [JC]

■ LENOGRASTIM**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 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 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 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 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 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.

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 Ewing's sarcoma.

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's lymphoma (intermediate or high grade).

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 osteosarcoma.

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 rhabdomyosarcoma.

Authority required

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

Authority required

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

Authority required

Assisting peripheral blood progenitor cell or bone marrow transplantation

Clinical criteria:

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

LENOGRASTIM Powder for injection 13,400,000 i.u. (105 micrograms) vial, 10

6337M	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2		11	..	*1019.74	Granocyte 13 [PF]

LENOGRASTIM Powder for injection 33,600,000 i.u. (263 micrograms) vial, 10

6338N	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2		11	..	*2485.86	Granocyte 34 [PF]

■ MEPOLIZUMAB

Note The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note For copies of the ACQ, please contact GlaxoSmithKline Medical Information on 1800 033 109.

Note It is recommended that an application for continuing treatment is submitted at the time of the 26 to 30 week assessment, to ensure continuity of treatment for those patients who meet the continuation criteria for PBS-subsidised mepolizumab treatment.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE EOSINOPHILIC ASTHMA

Patients are eligible to commence a 'mepolizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to mepolizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised mepolizumab therapy before they are eligible to commence the next mepolizumab treatment cycle, or if eligible, an 'omalizumab treatment cycle'. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised mepolizumab is stopped to the date of the first application for initial treatment with mepolizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised mepolizumab therapy:

(a) Initial treatment:

Applications for initial treatment should be made where:

- i) A patient has received no prior PBS-subsidised mepolizumab treatment and wishes to commence such therapy; or
- ii) A patient wishes to recommence treatment with mepolizumab following a break in PBS-subsidised therapy of more than 6 months; or
- iii) A patient has received prior PBS-subsidised omalizumab and wishes to commence treatment with mepolizumab after a treatment break of 6 months.

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 32 weeks of therapy for mepolizumab.

(b) Grandfather patients:

For patients who commenced treatment with mepolizumab for uncontrolled severe eosinophilic asthma prior to 1 January 2017 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment with mepolizumab will be authorised under this criterion. Approval will be based on the criteria included in the relevant restriction. Following completion of the initial PBS-subsidised course, further applications for treatment with mepolizumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). If a 'Grandfathered' patient recommences on second and subsequent cycles after a treatment break, the 'Grandfathered' patient must re-qualify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 6 month break in PBS-subsidised therapy' below for further details.

(c) Continuing treatment:

Following the completion of the initial treatment course with mepolizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with mepolizumab providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing mepolizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) and oral corticosteroid dose, submitted with the initial authority application for mepolizumab. However, prescribers may provide new baseline measurements when a new initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent mepolizumab treatment cycle, or an initial omalizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au/www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note 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

Uncontrolled severe eosinophilic asthma

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be under the care of the same physician for at least 12 months, **AND**
- Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have forced expiratory volume (FEV1) less than or equal to 80% predicted, documented on 1 or more occasions in the previous 12 months, **AND**
- Patient must have blood eosinophil count greater than or equal to 300 cells per microlitre in the last 6 weeks, **AND**
- Patient must have signed a patient or parent/guardian acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised omalizumab.

Population criteria:

- Patient must be aged 12 years or older.

Treatment criteria:

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Optimised asthma therapy includes:

- (i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; **AND**
- (ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

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

- (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, **AND**
- (b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient must be made at time of application for treatment (to establish baseline score) and again around 26 to 30 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment at around 26 to 30 weeks, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with mepolizumab.

A patient who fails to respond to a course of PBS-subsidised mepolizumab for the treatment of uncontrolled severe eosinophilic asthma will not be eligible to receive further PBS-subsidised treatment with mepolizumab or omalizumab within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request 7 repeats to provide for an initial course of mepolizumab sufficient for 32 weeks of therapy.

Mepolizumab and omalizumab may not be used concurrently or within 6 months of each other. A patient is required to have ceased treatment with omalizumab for 6 months prior to initiating treatment with mepolizumab.

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

- (a) a completed authority prescription form; and
- (b) a completed Severe Eosinophilic Asthma Initial PBS Authority Application - Supporting Information Form, which includes the following:
 - (i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and

- (ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
- (iii) the signed patient or parent/guardian acknowledgement; and
- (c) a copy of the eosinophil pathology report; and
- (d) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms.

mepolizumab 100 mg injection, 1 vial

11003D	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1		7	..	1685.02	Nucala [GK]

■ MEPOLIZUMAB

Note For copies of the ACQ, please contact GlaxoSmithKline Medical Information on 1800 033 109.

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE EOSINOPHILIC ASTHMA

Patients are eligible to commence a 'mepolizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to mepolizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised mepolizumab therapy before they are eligible to commence the next mepolizumab treatment cycle, or if eligible, an 'omalizumab treatment cycle'. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised mepolizumab is stopped to the date of the first application for initial treatment with mepolizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised mepolizumab therapy:

(a) Initial treatment:

Applications for initial treatment should be made where:

- i) A patient has received no prior PBS-subsidised mepolizumab treatment and wishes to commence such therapy; or
- ii) A patient wishes to recommence treatment with mepolizumab following a break in PBS-subsidised therapy of more than 6 months; or
- iii) A patient has received prior PBS-subsidised omalizumab and wishes to commence treatment with mepolizumab after a treatment break of 6 months.

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 32 weeks of therapy for mepolizumab.

(b) Grandfather patients:

For patients who commenced treatment with mepolizumab for uncontrolled severe eosinophilic asthma prior to 1 January 2017 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment with mepolizumab will be authorised under this criterion. Approval will be based on the criteria included in the relevant restriction. Following completion of the initial PBS-subsidised course, further applications for treatment with mepolizumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). If a 'Grandfathered' patient recommences on second and subsequent cycles after a treatment break, the 'Grandfathered' patient must re-qualify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 6 month break in PBS-subsidised therapy' below for further details.

(c) Continuing treatment:

Following the completion of the initial treatment course with mepolizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with mepolizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing mepolizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) and oral corticosteroid dose, submitted with the initial authority application for mepolizumab. However, prescribers may provide new baseline measurements when a new initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent mepolizumab treatment cycle, or an initial omalizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

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

Uncontrolled severe eosinophilic asthma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug, **AND**
- The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised omalizumab.

Population criteria:

- Patient must be aged 12 years or older.

Treatment criteria:

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

An adequate response to mepolizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline,

OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline.

All applications for continuing treatment with mepolizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, and the assessment of oral corticosteroid dose, must be made at around 26 to 30 weeks after the first dose of PBS-subsidised mepolizumab so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with mepolizumab. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with mepolizumab.

A patient who fails to respond to a course of PBS-subsidised mepolizumab for the treatment of uncontrolled severe eosinophilic asthma will not be eligible to receive further PBS-subsidised treatment with mepolizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate number of repeats to provide for a continuing course of mepolizumab sufficient for 24 weeks of therapy.

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

- (a) a completed authority prescription form; and
- (b) a completed Severe Eosinophilic Asthma Continuing PBS Authority Application - Supporting Information Form which includes details of maintenance oral corticosteroid dose; and
- (c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms

Note If the same physician cannot assess the patient please call the Department of Human Services on 1800 700 270.

Note It is recommended that second and subsequent applications for continuing treatment are submitted at the time of an 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criteria for PBS-subsidised mepolizumab treatment.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Uncontrolled severe eosinophilic asthma

Treatment Phase: Initial treatment - grandfather patients

Clinical criteria:

- Patient must have received non-PBS treatment with this drug for this condition prior to 1 January 2017, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- Patient must have had, prior to commencement of mepolizumab, a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) Forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days, **AND**
- Patient must have had blood eosinophil count greater than or equal to 300 cells per microlitre prior to commencement of mepolizumab, **AND**
- Patient must have had a duration of asthma of at least 1 year prior to commencement of mepolizumab, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy prior to mepolizumab therapy despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- Patient must have signed a patient or parent/guardian acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment, **AND**
- Patient must have demonstrated an adequate response to treatment with mepolizumab, **AND**
- The treatment must not be used in combination with omalizumab.

Population criteria:

- Patient must be aged 12 years or older.

Treatment criteria:

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.
- Optimised asthma therapy includes:
- (i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; AND
 - (ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.
- If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

A review of the patient's records should be conducted to extract pre- and post-mepolizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations. Parameters to establish response are: (i) a reduction in Asthma Control Questionnaire (ACQ-5) score of at least 0.5; and/or(ii) maintenance oral corticosteroid dose reduced by at least 25% from baseline.

The assessment of the patient's response to the initial PBS subsidised course of treatment must be made at around 18 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. The same parameters used to establish response to non-PBS-subsidised therapy with mepolizumab should be used for the assessment.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with mepolizumab.

Patients will be eligible to receive continuing courses of mepolizumab treatment of up to 24 weeks providing they continue to demonstrate an adequate response to treatment.

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

A patient who fails to respond to a course of PBS-subsidised mepolizumab for the treatment of uncontrolled severe eosinophilic asthma will not be eligible to receive further PBS-subsidised treatment with mepolizumab or omalizumab within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for a continuing course of mepolizumab sufficient for 24 weeks of therapy.

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

- (a) a completed authority prescription form; and
- (b) a completed Severe Eosinophilic Asthma Grandfather PBS Authority Application - Supporting Information Form, which includes the following:
 - (i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and
 - (ii) details of pre- and post-mepolizumab data on symptoms, quality of life, medication doses, severe exacerbation/s and hospitalisations, and
 - (iii) the signed patient or parent/guardian acknowledgement; and
- (c) a copy of the pre-mepolizumab eosinophil pathology report.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note It is recommended that an application for continuing treatment is submitted at the time of the 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS subsidised mepolizumab treatment.

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

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

Applications for authority to prescribe should be forwarded to:

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

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

mepolizumab 100 mg injection, 1 vial

11014Q	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1		5	..	1685.02	Nucala [GK]

■ OMALIZUMAB

Note Special Pricing Arrangements apply.

Authority required

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be under the care of the same physician for at least 12 months, **AND**
- Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have forced expiratory volume (FEV1) less than or equal to 80% predicted, documented on 1 or more occasions in the previous 12 months, **AND**
- Patient must have past or current evidence of atopy, documented by skin prick testing or RAST, **AND**
- Patient must have total serum human immunoglobulin E greater than or equal to 30 IU/mL, **AND**
- Patient must have signed a patient or parent/guardian acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised mepolizumab.

Population criteria:

- Patient must be aged 12 years or older.

Treatment criteria:

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Optimised asthma therapy includes:

- (i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; **AND**
- (ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The initial IgE assessment must be no more than 12 months old at the time of application.

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

- (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, **AND**
- (b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, must be made at around 22 to 26 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab or mepolizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

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

- (a) a completed authority prescription form; and
- (b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form, which includes the following:
 - (i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and
 - (ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
 - (iii) the signed patient or parent/guardian acknowledgement; and
 - (c) the IgE pathology report; and
 - (d) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note It is recommended that an application for continuing treatment is submitted at the time of the 22 to 26 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next omalizumab treatment cycle or, if eligible, a 'mepolizumab treatment cycle'. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab or mepolizumab treatment is stopped to the date of the first application for initial treatment with omalizumab or mepolizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy:

(a) Initial treatment:

Applications for initial treatment should be made where:

i) A patient has received no prior PBS-subsidised omalizumab treatment and wishes to commence such therapy; or

ii) A patient wishes to recommence treatment with omalizumab following a break in PBS-subsidised therapy of at least 6 months; or

iii) A patient has received prior PBS-subsidised mepolizumab and wishes to commence treatment with omalizumab after a treatment break of at least 6 months.

All applications for initial treatment for non-grandfathered patients will be limited to provide for a maximum of 28 weeks of therapy of omalizumab.

(b) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for omalizumab. For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent omalizumab treatment cycle, or an initial mepolizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Authority required

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 28 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction.

Treatment criteria:

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Note Authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Uncontrolled severe allergic asthma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have a documented history of severe allergic asthma, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised mepolizumab.

Population criteria:

- Patient must be aged 12 years or older.

Treatment criteria:

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

An adequate response to omalizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline, OR

(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline (this criterion is only applicable for patients transitioned from the paediatric to the adolescent/adult restriction).

All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, the assessment of oral corticosteroid dose, and the assessment of time adjusted exacerbation rate must be made at around 18 to 22 weeks after the first dose of PBS-subsidised omalizumab so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy.

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

(a) a completed authority prescription form(s); and

(b) a completed Severe Allergic Asthma PBS Authority Application and Supporting Information Form which includes details of maintenance oral corticosteroid dose; and

(c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms and is endorsed with the signature of the prescriber; for patients transitioned from the paediatric to the adolescent/adult restrictions an exacerbation calculation sheet may be submitted.

Note If the same physician cannot assess the patient please call the Department of Human Services on 1800 700 270.

Note For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note It is recommended that an application for continuing treatment is submitted at the time of the 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a

treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next omalizumab treatment cycle or, if eligible, a 'mepolizumab treatment cycle'. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab or mepolizumab treatment is stopped to the date of the first application for initial treatment with omalizumab or mepolizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy:

(a) Initial treatment:

Applications for initial treatment should be made where:

- i) A patient has received no prior PBS-subsidised omalizumab treatment and wishes to commence such therapy; or
- ii) A patient wishes to recommence treatment with omalizumab following a break in PBS-subsidised therapy of at least 6 months; or
- iii) A patient has received prior PBS-subsidised mepolizumab and wishes to commence treatment with omalizumab after a treatment break of at least 6 months.

All applications for initial treatment for non-grandfathered patients will be limited to provide for a maximum of 28 weeks of therapy of omalizumab.

(b) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for omalizumab. For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent omalizumab treatment cycle, or an initial mepolizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Authority required

Uncontrolled severe allergic asthma

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

omalizumab 150 mg/mL injection, 1 mL syringe

10122R	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	433.42	Xolair [NV]	

omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

10110D	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	220.22	Xolair [NV]	

▪ RIOCIQUAT

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 1 month following cessation of therapy, as recommended by the TGA-approved Product Information.

Note Special Pricing Arrangements apply.

Authority required

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have WHO Functional Class II, III or IV CTEPH, **AND**
- The condition must be inoperable by pulmonary endarterectomy; OR
- The condition must be recurrent or persistent following pulmonary endarterectomy, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated in a centre with expertise in the management of CTEPH.
- CTEPH that is inoperable by pulmonary endarterectomy is defined as follows:
- Right heart catheterisation (RHC) demonstrating pulmonary vascular resistance (PVR) of greater than 300 dyn*sec*cm⁻⁵ measured at least 90 days after start of full anticoagulation; and
 - A mean pulmonary artery pressure (PAPmean) of greater than 25 mmHg at least 90 days after start of full anticoagulation.
- CTEPH that is recurrent or persistent subsequent to pulmonary endarterectomy is defined as follows:
- RHC demonstrating a PVR of greater than 300 dyn*sec*cm⁻⁵ measured at least 180 days following pulmonary endarterectomy.

Where a RHC cannot be performed due to right ventricular dysfunction, an echocardiogram demonstrating the dysfunction must be provided at the time of application.

Applications for authorisation must be in writing and must include: (1) completed authority prescription forms sufficient for dose titration; and (2) a completed CTEPH PBS Initial Authority Application - Supporting Information form which includes results from the 3 tests below, to establish baseline measurements, where available: (i) RHC composite assessment, and (ii) ECHO composite assessment, and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgment form; and (4) confirmation of evidence of inoperable CTEPH including results of a pulmonary vascular resistance (PVR), a mean pulmonary artery pressure (PAPmean) and the starting date of full anticoagulation; or (5) confirmation of evidence of recurrent or persistent CTEPH including result of PVR and the date that pulmonary endarterectomy was performed; or (6) confirmation of an echocardiogram demonstrating right ventricular dysfunction.

Where it is not possible to perform all 3 tests above on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only.

In circumstance where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Prescriptions for dose titration must provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment. The quantity approved must be based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 3 repeats.

The assessment of the patient's response to the initial 20-week course of treatment should be made following the preceding 16 weeks of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

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

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must demonstrate stable or responding disease, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated in a centre with expertise in the management of CTEPH.

Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed CTEPH PBS Continuing Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to this drug is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease.

The assessment of the patient's response to the continuing 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

The maximum quantity per prescription must be based on the dosage recommendations in the TGA-approved Product Information and be limited to provide sufficient supply for 1 month of treatment.

A maximum of 5 repeats will be authorised.

Applications for continuing treatment with this drug should be made two weeks prior to the completion of the 6-month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate disease stability or improvement to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

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

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Grandfathered patients

Clinical criteria:

- Patient must have previously received treatment with this drug for this condition prior to 1 January 2017, **AND**
- Patient must have a documented history of WHO Functional Class II, III or IV CTEPH, **AND**
- The condition must be inoperable by pulmonary endarterectomy; OR
- The condition must be recurrent or persistent following pulmonary endarterectomy, **AND**
- The treatment must be the sole PBS-subsidised agent for this condition.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated in a centre with expertise in the management of CTEPH.

CTEPH that is inoperable by pulmonary endarterectomy is defined as follows:

- Right heart catheterisation (RHC) demonstrating pulmonary vascular resistance (PVR) of greater than $300 \text{ dyn} \cdot \text{sec} \cdot \text{cm}^{-5}$ measured at least 90 days after start of full anticoagulation; and
- A mean pulmonary artery pressure (PAPmean) of greater than 25 mmHg at least 90 days after start of full anticoagulation.

CTEPH that is recurrent or persistent subsequent to pulmonary endarterectomy is defined as follows:

- RHC demonstrating a PVR of greater than 300 dyn*sec*cm⁻⁵ measured at least 180 days following pulmonary endarterectomy.

Where a RHC cannot be performed due to right ventricular dysfunction, an echocardiogram demonstrating the dysfunction must be provided at the time of application.

Applications for authorisation must be in writing and must include: (1) A completed authority prescription form; and (2) a completed CTEPH PBS Initial Authority Application - Supporting Information form which includes results from the 3 tests below, to establish baseline measurements, where available: (i) RHC composite assessment, and (ii) ECHO composite assessment, and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgment form; and (4) confirmation of evidence of inoperable CTEPH including results of a pulmonary vascular resistance (PVR), a mean pulmonary artery pressure (PAPmean) and the starting date of full anticoagulation; or (5) confirmation of evidence of recurrent or persistent CTEPH including result of PVR and the date that pulmonary endarterectomy was performed; or (6) confirmation of an echocardiogram demonstrating right ventricular dysfunction.

Where it is not possible to perform all 3 tests above on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (2) RHC composite assessment only.

In circumstance where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

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

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

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

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this agent under the Initial treatment restriction to complete a maximum of 20 weeks of treatment; OR
- Patient must have received insufficient therapy with this agent under the Continuing treatment restriction to complete a maximum of 24 weeks of treatment; OR
- Patient must have received insufficient therapy with this agent under the Grandfathering restriction to complete a maximum of 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 20 or 24 weeks of treatment available under the above respective restriction, **AND**
- The treatment must be the sole PBS-subsidised agent for this condition.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated in a centre with expertise in the management of CTEPH.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

riociguat 1 mg tablet, 42

10990K

Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
1	..	..	..	1764.73	Adempas [BN]

riociguat 1 mg tablet, 84

11010L

Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
1	..	..	..	3482.44	Adempas [BN]

riociguat 1.5 mg tablet, 42

10974N	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1		..	..	1764.73	Adempas [BN]

riociguat 1.5 mg tablet, 84

10975P	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1		..	..	3482.44	Adempas [BN]

riociguat 2 mg tablet, 42

11012N	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1		..	..	1764.73	Adempas [BN]

riociguat 2 mg tablet, 84

11017W	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1		..	..	3482.44	Adempas [BN]

riociguat 2.5 mg tablet, 42

10985E	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1		..	..	1764.73	Adempas [BN]

riociguat 2.5 mg tablet, 84

11018X	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1		..	..	3482.44	Adempas [BN]

riociguat 500 microgram tablet, 42

11009K	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1		..	..	1764.73	Adempas [BN]

riociguat 500 microgram tablet, 84

11008J	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1		..	..	3482.44	Adempas [BN]

Highly Specialised Drugs Program (Public Hospital)

▪ AZITHROMYCIN

Authority required (STREAMLINED)

6356

Mycobacterium avium complex infection

Clinical criteria:

- The treatment must be for prophylaxis, **AND**
- Patient must be human immunodeficiency virus (HIV) positive, **AND**
- Patient must have CD4 cell counts of less than 75 per cubic millimetre.

azithromycin 600 mg tablet, 8

5616N	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2		5	..	*110.76	Zithromax [PF]

▪ CYCLOSPORIN

Caution Careful monitoring of patients is mandatory.

Authority required (STREAMLINED)

6628

Management of transplant rejection

Clinical criteria:

- The treatment must be used by organ or tissue transplant recipients.

cyclosporin 50 mg/mL injection, 10 x 1 mL ampoules

5631J	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1		..	..	54.10	Sandimmun [NV]

▪ CYCLOSPORIN

Caution Careful monitoring of patients is mandatory.

Authority required (STREAMLINED)

6643

Management of transplant rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must have had an organ or tissue transplantation, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Authority required (STREAMLINED)

6660

Severe atopic dermatitis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- The condition must be ineffective to other systemic therapies; OR
- The condition must be inappropriate for other systemic therapies.

Treatment criteria:

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologists.

Authority required (STREAMLINED)

6676

Severe psoriasis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- The condition must be ineffective to other systemic therapies; OR
- The condition must be inappropriate for other systemic therapies, **AND**

- The condition must have caused significant interference with quality of life.

Treatment criteria:

- Must be treated by a dermatologist.

Authority required (STREAMLINED)

6631

Nephrotic syndrome

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must have failed prior treatment with steroids and cytostatic drugs; OR
- Patient must be intolerant to treatment with steroids and cytostatic drugs; OR
- The condition must be considered inappropriate for treatment with steroids and cytostatic drugs, **AND**
- Patient must not have renal impairment.

Treatment criteria:

- Must be treated by a nephrologist.

Authority required (STREAMLINED)

6638

Severe active rheumatoid arthritis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- The condition must have been ineffective to prior treatment with classical slow -acting anti-rheumatic agents (including methotrexate); OR
- The condition must be considered inappropriate for treatment with slow -acting anti-rheumatic agents (including methotrexate).

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist.

cyclosporin 10 mg capsule, 60

5632K	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	..	*74.40	Neoral 10 [NV]

cyclosporin 100 mg capsule, 30

5636P	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	..	*546.40	^a Cyclosporin Sandoz [SZ]	^a Neoral 100 [NV]

cyclosporin 100 mg/mL oral liquid, 50 mL

5633L	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	5	..	..	*1263.16	Neoral [NV]

cyclosporin 25 mg capsule, 30

5634M	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	..	*128.88	^a Cyclosporin Sandoz [SZ]	^a Neoral 25 [NV]

cyclosporin 50 mg capsule, 30

5635N	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	..	*268.16	^a Cyclosporin Sandoz [SZ]	^a Neoral 50 [NV]

▪ **ECULIZUMAB**

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 4 repeats, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis). Please consult the approved PI for information about vaccination against meningococcal infection.

Note Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of, but not limited to:

- Active malignancy;
- Active HIV infection;
- Hematopoietic stem cell transplants;
- Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
- Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
- Active autoimmune diseases;

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

Note The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:

- Presenting clinical features, including history, acute treatment and medications;
- Results of testing for genetic mutations (if available);
- Family history of aHUS, especially in first-degree relatives;

- d) Patient's prior history of episodes of active and progressing TMA caused by aHUS;
- e) Exclusion of alternative causes of TMA;
- f) History of renal or other organ transplant (if any);
- g) Any other matters considered relevant by the prescriber.

In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

Note The Authority application should include the results of screening for genetic mutations known to confer a high risk of developing aHUS. The results of genetic screening should be provided whether or not a high-risk mutation has been identified.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au. Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment - Balance of Supply

Clinical criteria:

- Patient must have received PBS-subsidised initial supply of eculizumab for this condition, **AND**
- Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample, **AND**
- Patient must not receive more than 20 weeks supply under this restriction.

Treatment criteria:

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

ADAMTS-13 activity result must have been submitted to the Department of Human Services. In the case that a sample for ADAMTS-13 activity taken prior to plasma exchange or infusion was not available at the time of application for **Initial Treatment**, ADAMTS-13 activity must have been measured 1-2 weeks following the last plasma exchange or infusion, and must have been submitted to the Department of Human Services within 27 days of commencement of eculizumab. The date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of the last, if any, plasma exchange or infusion that was undertaken in the two weeks prior to collection of the ADAMTS-13 assay must also have been provided to Department of Human Services.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

eculizumab 300 mg/30 mL injection, 30 mL vial

10190H	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1		4	..	5937.50	Soliris [X]

■ ECULIZUMAB

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for four weeks of treatment, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note **WARNING:** Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis). Please consult the approved PI for information about vaccination against meningococcal infection.

Note Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of, but not limited to:

- a) Active malignancy;
- b) Active HIV infection;
- c) Hematopoietic stem cell transplants;
- d) Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
- e) Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
- f) Active autoimmune diseases;

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

Note The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:

- a) Presenting clinical features, including history, acute treatment and medications;
- b) Results of testing for genetic mutations (if available);
- c) Family history of aHUS, especially in first-degree relatives;
- d) Patient's prior history of episodes of active and progressing TMA caused by aHUS;
- e) Exclusion of alternative causes of TMA;
- f) History of renal or other organ transplant (if any);
- g) Any other matters considered relevant by the prescriber.

In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

Note The Authority application should include the results of screening for genetic mutations known to confer a high risk of developing aHUS. The results of genetic screening should be provided whether or not a high-risk mutation has been identified.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au. Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have active and progressing thrombotic microangiopathy (TMA) caused by aHUS, **AND**
- Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample taken prior to plasma exchange or infusion; or, if ADAMTS-13 activity was not collected prior to plasma exchange or infusion, patient must have platelet counts of greater than $30 \times 10^9/L$ and a serum creatinine of greater than $150 \mu\text{mol/L}$, **AND**
- Patient must have a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days, **AND**
- Patient must have clinical features of active organ damage or impairment, **AND**
- Patient must not receive more than 4 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

Evidence of active and progressing TMA is defined by the following:

(1) a platelet count of less than $150 \times 10^9/L$; and evidence of two of the following:

- (i) presence of schistocytes on blood film;
- (ii) low or absent haptoglobin;
- (iii) lactate dehydrogenase (LDH) above normal range;

OR

(2) in recipients of a kidney transplant for end-stage kidney disease due to aHUS, a kidney biopsy confirming TMA; **AND**

(3) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:

(a) kidney impairment as demonstrated by one of the following:

- (i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or
- (ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or
- (iii) a sCr of greater than the age-appropriate ULN in paediatric patients; or
- (iv) a renal biopsy consistent with aHUS;

- (b) onset of TMA-related neurological impairment;
- (c) onset of TMA-related cardiac impairment;
- (d) onset of TMA-related gastrointestinal impairment;
- (e) onset of TMA-related pulmonary impairment.

Claims of non-renal TMA-related organ damage should be made at the point of application for initial PBS-subsidised eculizumab (where possible), and should be supported by objective clinical measures. The prescriber's cover letter should establish that the observed organ damage is directly linked to active and progressing TMA, particularly when indirect causes such as severe thrombocytopenia, hypertension and acute renal failure are present at the time of the initial organ impairment.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

The authority application must be in writing and must include:

- (1) A completed authority prescription form; and
- (2) A completed aHUS eculizumab Authority Application Supporting Information Form - Initial PBS-subsidised eculizumab treatment; and
- (3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and
- (4) A detailed cover letter from the prescriber; and
- (5) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
- (6) A measurement of body weight at the time of application; and
- (7) The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion; the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the two weeks prior to collection of the ADAMTS-13 assay; and
- (8) In the case that a sample for ADAMTS-13 assay was not collected prior to plasma exchange or infusion, measurement of ADAMTS-13 activity must be taken 1-2 weeks following the last plasma exchange or infusion. The ADAMTS-13 result must be submitted to the Department of Human Services within 27 days of commencement of eculizumab treatment in order for the patient to be considered as eligible for further PBS-subsidised eculizumab treatment, under **Initial treatment 1-balance of supply**; and
- (9) A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days; and

(10) Evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA - related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records. All tests must have been performed within one month of application; and

(11) For all patients, a recent measurement of eGFR, platelets and two of either LDH, haptoglobin or schistocytes of no more than 1 week old at the time of application.

eculizumab 300 mg/30 mL injection, 30 mL vial

10191J	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5937.50	Soliris [XI]	

■ ECULIZUMAB

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 6 repeats, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note For patients who have received continuing treatment with PBS-subsidised eculizumab prior to 1 January 2016, this restriction is limited to 28 weeks of therapy.

Note WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis). Please consult the approved PI for information about vaccination against meningococcal infection.

Note Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of, but not limited to:

- Active malignancy;
- Active HIV infection;
- Hematopoietic stem cell transplants;
- Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
- Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
- Active autoimmune diseases;

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

Note The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:

- Presenting clinical features, including history, acute treatment and medications;
- Results of testing for genetic mutations (if available);
- Family history of aHUS, especially in first-degree relatives;
- Patient's prior history of episodes of active and progressing TMA caused by aHUS;
- Exclusion of alternative causes of TMA;
- History of renal or other organ transplant (if any);
- Any other matters considered relevant by the prescriber.

In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

Note The Authority application should include the results of screening for genetic mutations known to confer a high risk of developing aHUS. The results of genetic screening should be provided whether or not a high-risk mutation has been identified.

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

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

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Extended initial treatment - Assessment phase

Clinical criteria:

- Patient must have received treatment under the initial restriction with PBS subsidised eculizumab for this condition, **AND**
- Patient must have demonstrated on-going treatment response of PBS-subsidised eculizumab treatment for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must not receive more than 56 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

- (1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; **AND**
- (2) One of the following:

- a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or
 - b) an eGFR within +/- 25% from baseline; or
 - c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.
- PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure.

A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

A maximum of up to 56 weeks of treatment is allowed under this restriction, however an application must be submitted at 6 months, 12 months, 18 months and 24 months following commencing PBS-subsidised eculizumab.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

(1) A completed authority prescription form; and

(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Extended Initial treatment; and

(3) A detailed cover letter from the prescriber; and

(4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and

(5) A measurement of body weight at the time of application; and

(6) An identified genetic mutation, if applicable; and

(7) A family history of aHUS, if applicable; and

(8) A history of multiple episodes of aHUS before commencing eculizumab treatment, if applicable; and

(9) A history of kidney transplant, if applicable, (especially if required due to aHUS); and

(10) An inclusion of the individual consequences of recurrent disease, if applicable; and

(11) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and

(12) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and

(13) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

eculizumab 300 mg/30 mL injection, 30 mL vial

10525Y	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1		6	..	5937.50	Soliris [XI]

■ ECULIZUMAB

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

Note Eculizumab is not PBS subsidised to treat TMA caused by conditions other than aHUS, such as TMA occurring in the setting of, but not limited to:

a) Active malignancy;

b) Active HIV infection;

c) Hematopoietic stem cell transplants;

d) Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;

e) Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;

f) Active autoimmune diseases;

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

Note The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:

a) Presenting clinical features, including history, acute treatment and medications;

b) Results of testing for genetic mutations (if available);

c) Family history of aHUS, especially in first-degree relatives;

d) Patient's prior history of episodes of active and progressing TMA caused by aHUS;

e) Exclusion of alternative causes of TMA;

f) History of renal or other organ transplant (if any);

g) Any other matters considered relevant by the prescriber.

In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

Note The Authority application should include the results of screening for genetic mutations known to confer a high risk of developing aHUS. The results of genetic screening should be provided whether or not a high-risk mutation has been identified.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au. Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received treatment under Extended Initial restriction with PBS subsidised eculizumab for this condition, **AND**
- Patient must have demonstrated on-going treatment response of PBS-subsidised eculizumab treatment for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

- (1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; **AND**
- (2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure.

A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

- (1) A completed authority prescription form; and
- (2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and
- (3) A detailed cover letter from the prescriber; and
- (4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
- (5) A measurement of body weight at the time of application; and
- (6) An identified genetic mutation, if applicable; and
- (7) A family history of aHUS, if applicable; and
- (8) A history of multiple episodes of aHUS before recommencing eculizumab treatment, if applicable; and
- (9) A history of kidney transplant if applicable (especially if required due to aHUS); and
- (10) An inclusion of the individual consequences of recurrent disease, if applicable; and
- (11) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and
- (12) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
- (13) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Extended Continuing treatment

Clinical criteria:

- Patient must have received treatment under the Continuing treatment with PBS-subsidised eculizumab for this condition, **AND**
- Patient must have demonstrated on-going treatment response with PBS-subsidised eculizumab for this condition, **AND**
- Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must have a TMA-related cardiomyopathy as evidenced by left ventricular ejection fraction < 40% on current objective measurement; OR

- Patient must have severe TMA-related neurological impairment; OR
- Patient must have severe TMA-related gastrointestinal impairment; OR
- Patient must have severe TMA-related pulmonary impairment on current objective measurement; OR
- Patient must have grade 4 or 5 chronic kidney disease (eGFR of less than 30 mL/min); OR
- Patient must have a high risk of aHUS recurrence in the short term in the absence of continued treatment with eculizumab, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Treatment criteria:

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

- (1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND
- (2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

- (1) A completed authority prescription form; and
- (2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and
- (3) A detailed cover letter from the prescriber; and
- (4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
- (5) A measurement of body weight at the time of application; and
- (6) An identified genetic mutation, if applicable; and
- (7) A family history of aHUS, if applicable; and
- (8) A history of multiple episodes of aHUS before commencing eculizumab treatment, if applicable; and
- (9) A history of kidney transplant, if applicable (especially if required due to aHUS); and
- (10) An inclusion of the individual consequences of recurrent disease; and
- (11) A supporting statement with clinical evidence of severe TMA-related cardiomyopathy (including current LVEF result), neurological impairment, gastrointestinal impairment or pulmonary impairment; and
- (12) Evidence that the patient has had a treatment response including haematological results of no more than 1 month old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 month old at the time of application; and
- (13) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
- (14) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

Note All applications should be accompanied by a detailed letter that outlines the objective evidence of high risk of critical organ damage if aHUS recurs. The following evidence may be submitted to establish the patient's level of risk of aHUS recurrence in the short term in the absence of continued treatment with eculizumab:

- a) Evidence of a mutation known to confer a high risk of aHUS recurrence;
- b) Past history of recurrent episodes of active and progressive TMA due to aHUS, prior to the episode that led to current use of eculizumab;
- c) Past family history of aHUS recurrence, especially in first-degree relatives;
- d) Past history of recurrent aHUS following renal transplant for end-stage renal failure due to aHUS.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Recommencement of treatment

Clinical criteria:

- Patient must have demonstrated treatment response to previous treatment with PBS-subsidised eculizumab for this condition, **AND**
- Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**

- Patient must have the following clinical conditions: (i) either significant haemolysis as measured by low /absent haptoglobin; or presence of schistocytes on the blood film; or lactate dehydrogenase (LDH) above normal; AND (ii) either platelet consumption as measured by either 25% decline from patient baseline or thrombocytopenia (platelet count $<150 \times 10^9/L$); OR (iii) TMA-related organ impairment including on recent biopsy, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

- (1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND
- (2) One of the following:
 - a) An increase in eGFR of $> 25\%$ from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or
 - b) an eGFR within $\pm 25\%$ from baseline; or
 - c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

- (1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or
- (2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

- (1) A completed authority prescription form(s); and
- (2) A completed aHUS eculizumab Authority Application Supporting Information Form for Recommencement of treatment; and
- (3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and
- (4) A detailed cover letter from the prescriber; and
- (5) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
- (6) A measurement of body weight at the time of application, and
- (7) An identified genetic mutation, if applicable; and
- (8) A family history of aHUS if applicable; and
- (9) A history of multiple episodes of aHUS following the treatment break, if applicable; and
- (10) A history of kidney transplant if applicable (especially if required due to aHUS); and
- (11) An inclusion of the individual consequences of recurrent disease; and
- (12) A supporting statement with clinical evidence of TMA-related organ damage including current (within one week of application) haematological results (platelet count, haptoglobin and LDH), eGFR level, and, if applicable, on recent biopsy;
- (13) Evidence that the patient has had a treatment response to their previous treatment with eculizumab; and
- (14) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
- (15) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

Note A raise in LDH alone is not a sufficient reason to re-commence eculizumab, but thrombocytopenia with one marker of haemolysis (such as raised LDH, presence of schistocytes, or low /absence of haptoglobin) is an accepted reason to consider re-commencement of eculizumab treatment.

Note Kidney transplantation/dialysis is not a contraindication to recommencement of eculizumab treatment.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing recommencement of treatment

Clinical criteria:

- Patient must have received treatment under Recommencement of treatment restriction with PBS-subsidised eculizumab for this condition, **AND**
- Patient must have demonstrated ongoing treatment response to the previous 24 weeks of PBS-subsidised eculizumab for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

- (1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

- a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or
- b) an eGFR within +/- 25% from baseline; or
- c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

- (1) A completed authority prescription form; and
- (2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and
- (3) A detailed cover letter from the prescriber; and
- (4) A copy of a current Certificate of vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed; and
- (5) A measurement of body weight at the time of application; and
- (6) An identified genetic mutation, if applicable; and
- (7) A family history of aHUS, if applicable; and
- (8) A history of multiple episodes of aHUS before recommencing eculizumab treatment, if applicable; and
- (9) A history of kidney transplant if applicable (especially if required due to aHUS); and
- (10) An inclusion of the individual consequences of recurrent disease, if applicable; and
- (11) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and
- (12) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
- (13) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

eculizumab 300 mg/30 mL injection, 30 mL vial

10183Y	Max. Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1		5	..	5937.50	Soliris [X]

■ FILGRASTIM

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.

Authority required (STREAMLINED)

6653

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

Authority required (STREAMLINED)

6654

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

Authority required (STREAMLINED)

6679

Assisting bone marrow transplantation

Clinical criteria:

- Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

Authority required (STREAMLINED)

6655

Assisting autologous peripheral blood progenitor cell transplantation

Clinical criteria:

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

Authority required (STREAMLINED)

6680

Severe congenital neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, **AND**
- Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

Authority required (STREAMLINED)

6621

Severe chronic neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; OR
- Patient must have neutrophil dysfunction, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

Authority required (STREAMLINED)

6640

Chronic cyclical neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, **AND**

- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

filgrastim 120 microgram/0.2 mL injection, 10 x 0.2 mL syringes

5829T	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2		11	..	*463.38	Nivestim [PF]

filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes

1123D	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2		11	..	*1158.44	TevaGrastim [TB]

filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes

5742F	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2		11	..	*1158.44	Neupogen [AN]

filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes

9692D	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2		11	..	*1158.44	Nivestim [PF]

filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes

2758E	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4		11	..	*1158.44	Zarzio [SZ]

filgrastim 300 microgram/mL injection, 10 x 1 mL vials

5741E	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2		11	..	*1158.44	Neupogen [AN]

filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes

5744H	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2		11	..	*1857.06	Neupogen [AN]

filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes

9694F	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2		11	..	*1857.06	Nivestim [PF]

filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes

2783L	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4		11	..	*1857.04	Zarzio [SZ]

filgrastim 480 microgram/0.8 mL injection, 10 x 0.8 mL syringes

1126G	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2		11	..	*1857.06	TevaGrastim [TB]

filgrastim 480 microgram/1.6 mL injection, 10 x 1.6 mL vials

5743G	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2		11	..	*1857.06	Neupogen [AN]

■ GRAZOPREVIR + ELBASVIR

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

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.

grazoprevir 100 mg + elbasvir 50 mg tablet, 28

10978T	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1		2	..	21000.00	Zepatier [MK]

■ GRAZOPRE VIR + ELBASVIR

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

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 16 weeks.

grazoprevir 100 mg + elbasvir 50 mg tablet, 28

10986F	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1		3	..	21000.00	Zepatier [MK]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of infliximab, vedolizumab and adalimumab for adult patients with ulcerative colitis. Patients are eligible for PBS-subsidised treatment with either infliximab, vedolizumab or adalimumab at any one time. From 1 December 2016, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial each of PBS-subsidised infliximab, vedolizumab or adalimumab without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with infliximab, vedolizumab or adalimumab while they continue to show a response to therapy. A patient who received PBS-subsidised infliximab, vedolizumab or adalimumab treatment prior to 1 December 2016 is considered to be in their first cycle as of 1 December 2016. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised infliximab, vedolizumab or adalimumab more than once. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised infliximab, vedolizumab or adalimumab treatment in the most recent cycle to the date of the first application for initial treatment with infliximab, vedolizumab or adalimumab under the new treatment cycle. A patient who has failed fewer than 3 trials of either infliximab, vedolizumab or adalimumab in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

(1) How to prescribe PBS-subsidised treatment with infliximab, vedolizumab and adalimumab after therapy after 1 December 2016.

(a) Initial treatment. Applications for initial treatment should be made where:

- (i) an adult patient has received no prior PBS-subsidised treatment with infliximab, vedolizumab or adalimumab in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) an adult patient has received prior PBS-subsidised (initial or continuing) infliximab, vedolizumab or adalimumab therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iii) an adult patient wishes to re-commence treatment with infliximab, vedolizumab or adalimumab following a break in PBS-subsidised therapy with the same agent (Initial 2).

Treatment authorisations under Initial 1 and Initial 2 will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab and vedolizumab.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab, and this assessment must be provided to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist. For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is provided to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with infliximab, vedolizumab or adalimumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment. Assessments of response to a course of PBS-subsidised therapy must be provided to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised treatment is approved, a patient may swap if eligible to the alternate infliximab, vedolizumab or adalimumab treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy. A patient may trial an alternate treatment at any time, regardless of whether they are receiving therapy (initial or continuing) with infliximab, vedolizumab or adalimumab at the time of the application. However, they cannot swap to a particular therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. To avoid confusion, an application for a patient who wishes to swap to the alternate infliximab,

vedolizumab or adalimumab therapy should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Mayo clinic score or partial Mayo clinic score submitted with the first authority application for infliximab, vedolizumab or adalimumab. However, prescribers may provide new baseline measurements any time other than when an initial treatment authority application is provided within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

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

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised infliximab, vedolizumab or adalimumab therapy of at least 5 years, must requalify for initial treatment with respect to the scores of disease severity. A patient must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for induction of remission for a minimum of 3 consecutive months, and, either azathioprine or 6-mercaptopurine for a minimum of 3 consecutive months or a tapered course of oral steroids over a 6 week period followed by an appropriately dosed thiopurine agent for a minimum of 3 consecutive months (unless intolerance develops necessitating permanent treatment withdrawal to these agents) immediately prior to the time the Mayo score is measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for moderate to severe ulcerative colitis prior to 1 December 2016 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 3 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

Note Special Pricing Arrangements apply.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment (new patient or Re commencement of treatment after more than 5 years break in therapy - Initial 1)

Clinical criteria:

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years; OR
- Patient must have previously received induction therapy with this drug for an acute severe episode of ulcerative colitis in the last 4 months and demonstrated an adequate response to induction therapy by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a PUCAI score less than 10 (if aged 6 to 17 years).

Population criteria:

- Patient must be 6 years of age or older.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

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

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the signed patient acknowledgement or guardian acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, or to be administered at 8-weekly intervals for patients who have received prior treatment for an acute severe episode, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 1 month old at the time of application.

Where treatment for an acute severe episode has occurred, an adequate response to induction therapy needs to be demonstrated by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 (if aged 6 to 17 years), within the first 12 weeks of receiving this drug for acute severe ulcerative colitis.

Patients who fail to achieve a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 within the first 12 weeks of receiving this drug for ulcerative colitis, or have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or have failed to maintain a PUCAI score less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose for patients administered doses at weeks 0, 2 and 6 (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The patient or guardian (required if patient is aged 6 to 17 years) must have signed a patient acknowledgement indicating that he or she understands and acknowledges that the PBS-subsidised treatment will cease if he or she does not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

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

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 while receiving treatment with this drug, if aged 6 to 17 years.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

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

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

Up to a maximum of 2 repeats will be authorised.

Note No applications for increased repeats will be authorised.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Change or Re-commencement of treatment after a break in therapy (Initial 2)

Clinical criteria:

- Patient must have previously been issued with an authority prescription for adalimumab, infliximab or vedolizumab for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of this drug within the timelines specified in the relevant restriction. If the response assessment to the previous course of this drug is not submitted as detailed in the relevant restriction, the patient will be deemed to have failed therapy with this drug.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

Up to a maximum of 2 repeats will be authorised.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.

Note No applications for increased repeats will be authorised.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (Change or Re commencement of treatment after a break in therapy) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 3 doses (Initial 1 and Initial 2 restrictions) or 2 repeats (Continuing restriction).

Population criteria:

- Patient must be 6 years of age or older.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.

infliximab 100 mg injection, 1 vial

10196P	Max. Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	..	574.85	^a Inflectra [PF]	^a Remicade [JC]

■ LENOGRASTIM**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)

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)

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)

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)

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)

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.

Authority required (STREAMLINED)

6644

Chemotherapy-induced neutropenia

Clinical criteria:

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

Authority required (STREAMLINED)

6673

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's lymphoma (intermediate or high grade).

Authority required (STREAMLINED)

6634

Chemotherapy-induced neutropenia

Clinical criteria:

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

Authority required (STREAMLINED)

6682

Chemotherapy-induced neutropenia

Clinical criteria:

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

Authority required (STREAMLINED)

6653

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

Authority required (STREAMLINED)

6654

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

Authority required (STREAMLINED)

6657

Assisting peripheral blood progenitor cell or bone marrow transplantation

Clinical criteria:

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

LENOGRASTIM Powder for injection 13,400,000 i.u. (105 micrograms) vial, 10

5787N	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2		11	..	*973.76	Granocyte 13 [PF]

LENOGRASTIM Powder for injection 33,600,000 i.u. (263 micrograms) vial, 10

5788P	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2		11	..	*2438.84	Granocyte 34 [PF]

■ MEPOLIZUMAB

Note The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note For copies of the ACQ, please contact GlaxoSmithKline Medical Information on 1800 033 109.

Note It is recommended that an application for continuing treatment is submitted at the time of the 26 to 30 week assessment, to ensure continuity of treatment for those patients who meet the continuation criteria for PBS-subsidised mepolizumab treatment.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE EOSINOPHILIC ASTHMA

Patients are eligible to commence a 'mepolizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to mepolizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised mepolizumab therapy before they are eligible to commence the next mepolizumab treatment cycle, or if eligible, an 'omalizumab treatment cycle'. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised mepolizumab is stopped to the date of the first application for initial treatment with mepolizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised mepolizumab therapy:

(a) Initial treatment:

Applications for initial treatment should be made where:

- A patient has received no prior PBS-subsidised mepolizumab treatment and wishes to commence such therapy; or
- A patient wishes to recommence treatment with mepolizumab following a break in PBS-subsidised therapy of more than 6 months; or
- A patient has received prior PBS-subsidised omalizumab and wishes to commence treatment with mepolizumab after a treatment break of 6 months.

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 32 weeks of therapy for mepolizumab.

(b) Grandfather patients:

For patients who commenced treatment with mepolizumab for uncontrolled severe eosinophilic asthma prior to 1 January 2017 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment with mepolizumab will be authorised under this criterion. Approval will be based on the criteria included in the relevant restriction. Following completion of the Initial PBS-subsidised course, further applications for treatment with mepolizumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing

treatment course/s). If a 'Grandfathered' patient recommences on second and subsequent cycles after a treatment break, the 'Grandfathered' patient must re-qualify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 6 month break in PBS-subsidised therapy' below for further details.

(c) Continuing treatment:

Following the completion of the initial treatment course with mepolizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with mepolizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing mepolizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) and oral corticosteroid dose, submitted with the initial authority application for mepolizumab. However, prescribers may provide new baseline measurements when a new initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent mepolizumab treatment cycle, or an initial omalizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note 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

Uncontrolled severe eosinophilic asthma

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be under the care of the same physician for at least 12 months, **AND**
- Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have forced expiratory volume (FEV1) less than or equal to 80% predicted, documented on 1 or more occasions in the previous 12 months, **AND**
- Patient must have blood eosinophil count greater than or equal to 300 cells per microlitre in the last 6 weeks, **AND**
- Patient must have signed a patient or parent/guardian acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised omalizumab.

Population criteria:

- Patient must be aged 12 years or older.

Treatment criteria:

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Optimised asthma therapy includes:

(i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; **AND**

(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

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

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, **AND**

(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient must be made at time of application for treatment (to establish baseline score) and again around 26 to 30 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment at around 26 to 30 weeks, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with mepolizumab.

A patient who fails to respond to a course of PBS-subsidised mepolizumab for the treatment of uncontrolled severe eosinophilic asthma will not be eligible to receive further PBS-subsidised treatment with mepolizumab or omalizumab within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request 7 repeats to provide for an initial course of mepolizumab sufficient for 32 weeks of therapy.

Mepolizumab and omalizumab may not be used concurrently or within 6 months of each other. A patient is required to have ceased treatment with omalizumab for 6 months prior to initiating treatment with mepolizumab.

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

- (a) a completed authority prescription form; and
- (b) a completed Severe Eosinophilic Asthma Initial PBS Authority Application - Supporting Information Form, which includes the following:
 - (i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and
 - (ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
 - (iii) the signed patient or parent/guardian acknowledgement; and
- (c) a copy of the eosinophil pathology report; and
- (d) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms.

mepolizumab 100 mg injection, 1 vial

10996R	Max. Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1		7	..	1638.00	Nucala [GK]

■ MEPOLIZUMAB

Note For copies of the ACQ, please contact GlaxoSmithKline Medical Information on 1800 033 109.

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE EOSINOPHILIC ASTHMA

Patients are eligible to commence a 'mepolizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to mepolizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised mepolizumab therapy before they are eligible to commence the next mepolizumab treatment cycle, or if eligible, an 'omalizumab treatment cycle'. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised mepolizumab is stopped to the date of the first application for initial treatment with mepolizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised mepolizumab therapy:

(a) Initial treatment:

Applications for initial treatment should be made where:

- i) A patient has received no prior PBS-subsidised mepolizumab treatment and wishes to commence such therapy; or
- ii) A patient wishes to recommence treatment with mepolizumab following a break in PBS-subsidised therapy of more than 6 months; or
- iii) A patient has received prior PBS-subsidised omalizumab and wishes to commence treatment with mepolizumab after a treatment break of 6 months.

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 32 weeks of therapy for mepolizumab.

(b) Grandfather patients:

For patients who commenced treatment with mepolizumab for uncontrolled severe eosinophilic asthma prior to 1 January 2017 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment with mepolizumab will be authorised under this criterion. Approval will be based on the criteria included in the relevant restriction. Following completion of the Initial PBS-subsidised course, further applications for treatment with mepolizumab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). If a 'Grandfathered' patient recommences on second and subsequent cycles after a treatment break, the 'Grandfathered' patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 6 month break in PBS-subsidised therapy' below for further details.

(c) Continuing treatment:

Following the completion of the initial treatment course with mepolizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with mepolizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing mepolizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) and oral corticosteroid dose, submitted with the Initial authority application for mepolizumab. However, prescribers may provide new baseline measurements when

a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent mepolizumab treatment cycle, or an initial omalizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

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

Uncontrolled severe eosinophilic asthma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug, **AND**
- The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised omalizumab.

Population criteria:

- Patient must be aged 12 years or older.

Treatment criteria:

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

An adequate response to mepolizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline,

OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline.

All applications for continuing treatment with mepolizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, and the assessment of oral corticosteroid dose, must be made at around 26 to 30 weeks after the first dose of PBS-subsidised mepolizumab so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with mepolizumab. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with mepolizumab.

A patient who fails to respond to a course of PBS-subsidised mepolizumab for the treatment of uncontrolled severe eosinophilic asthma will not be eligible to receive further PBS-subsidised treatment with mepolizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate number of repeats to provide for a continuing course of mepolizumab sufficient for 24 weeks of therapy.

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

- (a) a completed authority prescription form; and
- (b) a completed Severe Eosinophilic Asthma Continuing PBS Authority Application - Supporting Information Form which includes details of maintenance oral corticosteroid dose; and
- (c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms

Note If the same physician cannot assess the patient please call the Department of Human Services on 1800 700 270.

Note It is recommended that second and subsequent applications for continuing treatment are submitted at the time of an 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criteria for PBS-subsidised mepolizumab treatment.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Uncontrolled severe eosinophilic asthma

Treatment Phase: Initial treatment - grandfather patients

Clinical criteria:

- Patient must have received non-PBS treatment with this drug for this condition prior to 1 January 2017, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- Patient must have had, prior to commencement of mepolizumab, a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with

severe asthma, defined by the following standard clinical features: (i) Forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or(ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or(iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days, **AND**

- Patient must have had blood eosinophil count greater than or equal to 300 cells per microlitre prior to commencement of mepolizumab, **AND**
- Patient must have had a duration of asthma of at least 1 year prior to commencement of mepolizumab, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy prior to mepolizumab therapy despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- Patient must have signed a patient or parent/guardian acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment, **AND**
- Patient must have demonstrated an adequate response to treatment with mepolizumab, **AND**
- The treatment must not be used in combination with omalizumab.

Population criteria:

- Patient must be aged 12 years or older.

Treatment criteria:

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Optimised asthma therapy includes:

(i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; **AND**

(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

A review of the patient's records should be conducted to extract pre- and post-mepolizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations. Parameters to establish response are: (i) a reduction in Asthma Control Questionnaire (ACQ-5) score of at least 0.5; and/or(ii) maintenance oral corticosteroid dose reduced by at least 25% from baseline.

The assessment of the patient's response to the initial PBS subsidised course of treatment must be made at around 18 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. The same parameters used to establish response to non-PBS-subsidised therapy with mepolizumab should be used for the assessment.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with mepolizumab.

Patients will be eligible to receive continuing courses of mepolizumab treatment of up to 24 weeks providing they continue to demonstrate an adequate response to treatment.

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

A patient who fails to respond to a course of PBS-subsidised mepolizumab for the treatment of uncontrolled severe eosinophilic asthma will not be eligible to receive further PBS-subsidised treatment with mepolizumab or omalizumab within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for a continuing course of mepolizumab sufficient for 24 weeks of therapy.

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

- (a) a completed authority prescription form; and
- (b) a completed Severe Eosinophilic Asthma Grandfather PBS Authority Application - Supporting Information Form, which includes the following:
 - (i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and
 - (ii) details of pre- and post-mepolizumab data on symptoms, quality of life, medication doses, severe exacerbation/s and hospitalisations, and
 - (iii) the signed patient or parent/guardian acknowledgement; and
 - (c) a copy of the pre-mepolizumab eosinophil pathology report.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note It is recommended that an application for continuing treatment is submitted at the time of the 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS subsidised mepolizumab treatment.

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

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

Applications for authority to prescribe should be forwarded to:

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

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

mepolizumab 100 mg injection, 1 vial

10980X	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1		5	..	1638.00	Nucala [GK]

■ OMALIZUMAB

Note Special Pricing Arrangements apply.

Authority required

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be under the care of the same physician for at least 12 months, **AND**
- Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have forced expiratory volume (FEV1) less than or equal to 80% predicted, documented on 1 or more occasions in the previous 12 months, **AND**
- Patient must have past or current evidence of atopy, documented by skin prick testing or RAST, **AND**
- Patient must have total serum human immunoglobulin E greater than or equal to 30 IU/mL, **AND**
- Patient must have signed a patient or parent/guardian acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised mepolizumab.

Population criteria:

- Patient must be aged 12 years or older.

Treatment criteria:

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Optimised asthma therapy includes:

(i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; **AND**

(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The initial IgE assessment must be no more than 12 months old at the time of application.

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

- (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, **AND**
- (b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, must be made at around 22 to 26 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab or mepolizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

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

(a) a completed authority prescription form; and

(b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form,

which includes the following:

(i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and

(ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(iii) the signed patient or parent/guardian acknowledgement; and

(c) the IgE pathology report; and

(d) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note It is recommended that an application for continuing treatment is submitted at the time of the 22 to 26 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next omalizumab treatment cycle or, if eligible, a 'mepolizumab treatment cycle'. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab or mepolizumab treatment is stopped to the date of the first application for initial treatment with omalizumab or mepolizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy:

(a) Initial treatment:

Applications for initial treatment should be made where:

i) A patient has received no prior PBS-subsidised omalizumab treatment and wishes to commence such therapy; or

ii) A patient wishes to recommence treatment with omalizumab following a break in PBS-subsidised therapy of at least 6 months; or

iii) A patient has received prior PBS-subsidised mepolizumab and wishes to commence treatment with omalizumab after a treatment break of at least 6 months.

All applications for initial treatment for non-grandfathered patients will be limited to provide for a maximum of 28 weeks of therapy of omalizumab.

(b) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the initial authority application for omalizumab. For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response. However, prescribers may provide new baseline measurements when a new initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent omalizumab treatment cycle, or an initial mepolizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum

period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Authority required

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 28 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction.

Treatment criteria:

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Note Authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Uncontrolled severe allergic asthma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have a documented history of severe allergic asthma, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised mepolizumab.

Population criteria:

- Patient must be aged 12 years or older.

Treatment criteria:

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

An adequate response to omalizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline, OR

(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline (this criterion is only applicable for patients transitioned from the paediatric to the adolescent/adult restriction).

All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, the assessment of oral corticosteroid dose, and the assessment of time adjusted exacerbation rate must be made at around 18 to 22 weeks after the first dose of PBS-subsidised omalizumab so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy.

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

(a) a completed authority prescription form(s); and

(b) a completed Severe Allergic Asthma PBS Authority Application and Supporting Information Form which includes details of maintenance oral corticosteroid dose; and

(c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms and is endorsed with the signature of the prescriber; for patients transitioned from the paediatric to the adolescent/adult restrictions an exacerbation calculation sheet may be submitted.

Note If the same physician cannot assess the patient please call the Department of Human Services on 1800 700 270.

Note For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note It is recommended that an application for continuing treatment is submitted at the time of the 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next omalizumab treatment cycle or, if eligible, a 'mepolizumab treatment cycle'. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab or mepolizumab treatment is stopped to the date of the first application for initial treatment with omalizumab or mepolizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy:

(a) Initial treatment:

Applications for initial treatment should be made where:

i) A patient has received no prior PBS-subsidised omalizumab treatment and wishes to commence such therapy; or

ii) A patient wishes to recommence treatment with omalizumab following a break in PBS-subsidised therapy of at least 6 months; or

iii) A patient has received prior PBS-subsidised mepolizumab and wishes to commence treatment with omalizumab after a treatment break of at least 6 months.

All applications for initial treatment for non-grandfathered patients will be limited to provide for a maximum of 28 weeks of therapy of omalizumab.

(b) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the initial authority application for omalizumab. For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response. However, prescribers may provide new baseline measurements when a new initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent omalizumab treatment cycle, or an initial mepolizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Authority required

Uncontrolled severe allergic asthma

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

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

omalizumab 150 mg/mL injection, 1 mL syringe

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

omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

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

■ RIOCIGUAT

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 1 month following cessation of therapy, as recommended by the TGA-approved Product Information.

Note Special Pricing Arrangements apply.

Authority required

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have WHO Functional Class II, III or IV CTEPH, **AND**
- The condition must be inoperable by pulmonary endarterectomy; OR
- The condition must be recurrent or persistent following pulmonary endarterectomy, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated in a centre with expertise in the management of CTEPH.

CTEPH that is inoperable by pulmonary endarterectomy is defined as follows:

- Right heart catheterisation (RHC) demonstrating pulmonary vascular resistance (PVR) of greater than 300 dyn*sec*cm⁻⁵ measured at least 90 days after start of full anticoagulation; and
- A mean pulmonary artery pressure (PAPmean) of greater than 25 mmHg at least 90 days after start of full anticoagulation.

CTEPH that is recurrent or persistent subsequent to pulmonary endarterectomy is defined as follows:

- RHC demonstrating a PVR of greater than 300 dyn*sec*cm⁻⁵ measured at least 180 days following pulmonary endarterectomy.

Where a RHC cannot be performed due to right ventricular dysfunction, an echocardiogram demonstrating the dysfunction must be provided at the time of application.

Applications for authorisation must be in writing and must include: (1) completed authority prescription forms sufficient for dose titration; and (2) a completed CTEPH PBS Initial Authority Application - Supporting Information form which includes results from the 3 tests below, to establish baseline measurements, where available: (i) RHC composite assessment, and (ii) ECHO composite assessment, and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgment form; and (4) confirmation of evidence of inoperable CTEPH including results of a pulmonary vascular resistance (PVR), a mean pulmonary artery pressure (PAPmean) and the starting date of full anticoagulation; or (5) confirmation of evidence of recurrent or persistent CTEPH including result of PVR and the date that pulmonary endarterectomy was performed; or (6) confirmation of an echocardiogram demonstrating right ventricular dysfunction.

Where it is not possible to perform all 3 tests above on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only.

In circumstance where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Prescriptions for dose titration must provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment. The quantity approved must be based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 3 repeats.

The assessment of the patient's response to the initial 20-week course of treatment should be made following the preceding 16 weeks of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

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

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must demonstrate stable or responding disease, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated in a centre with expertise in the management of CTEPH.

Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed CTEPH PBS Continuing Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to this drug is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease.

The assessment of the patient's response to the continuing 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

The maximum quantity per prescription must be based on the dosage recommendations in the TGA-approved Product Information and be limited to provide sufficient supply for 1 month of treatment.

A maximum of 5 repeats will be authorised.

Applications for continuing treatment with this drug should be made two weeks prior to the completion of the 6-month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate disease stability or improvement to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

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

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Grandfathered patients

Clinical criteria:

- Patient must have previously received treatment with this drug for this condition prior to 1 January 2017, **AND**
- Patient must have a documented history of WHO Functional Class II, III or IV CTEPH, **AND**
- The condition must be inoperable by pulmonary endarterectomy; OR
- The condition must be recurrent or persistent following pulmonary endarterectomy, **AND**
- The treatment must be the sole PBS-subsidised agent for this condition.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated in a centre with expertise in the management of CTEPH.

CTEPH that is inoperable by pulmonary endarterectomy is defined as follows:

- Right heart catheterisation (RHC) demonstrating pulmonary vascular resistance (PVR) of greater than 300 dyn*sec*cm⁻⁵ measured at least 90 days after start of full anticoagulation; and
- A mean pulmonary artery pressure (PAPmean) of greater than 25 mmHg at least 90 days after start of full anticoagulation.

CTEPH that is recurrent or persistent subsequent to pulmonary endarterectomy is defined as follows:

- RHC demonstrating a PVR of greater than 300 dyn*sec*cm⁻⁵ measured at least 180 days following pulmonary endarterectomy.

Where a RHC cannot be performed due to right ventricular dysfunction, an echocardiogram demonstrating the dysfunction must be provided at the time of application.

Applications for authorisation must be in writing and must include: (1) A completed authority prescription form; and (2) a completed CTEPH PBS Initial Authority Application - Supporting Information form which includes results from the 3 tests below, to establish baseline measurements, where available: (i) RHC composite assessment, and (ii) ECHO composite assessment, and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgment form; and (4) confirmation of evidence of inoperable CTEPH including results of a pulmonary vascular resistance (PVR), a mean pulmonary artery pressure (PAPmean) and the starting date of full anticoagulation; or (5) confirmation of evidence of recurrent or persistent CTEPH including result of PVR and the date that pulmonary endarterectomy was performed; or (6) confirmation of an echocardiogram demonstrating right ventricular dysfunction.

Where it is not possible to perform all 3 tests above on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (2) RHC composite assessment only.

In circumstance where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

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

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

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

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this agent under the Initial treatment restriction to complete a maximum of 20 weeks of treatment; OR
- Patient must have received insufficient therapy with this agent under the Continuing treatment restriction to complete a maximum of 24 weeks of treatment; OR
- Patient must have received insufficient therapy with this agent under the Grandfathering restriction to complete a maximum of 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 20 or 24 weeks of treatment available under the above respective restriction, **AND**
- The treatment must be the sole PBS-subsidised agent for this condition.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated in a centre with expertise in the management of CTEPH.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

riociguat 1 mg tablet, 42

10976Q	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1		..	..	1717.71	Adempas [BN]

riociguat 1 mg tablet, 84

11020B	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1		..	..	3435.42	Adempas [BN]

riociguat 1.5 mg tablet, 42

10989J	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1		..	..	1717.71	Adempas [BN]

riociguat 1.5 mg tablet, 84

10977R	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1		..	..	3435.42	Adempas [BN]

riociguat 2 mg tablet, 42

10984D	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1		..	..	1717.71	Adempas [BN]

riociguat 2 mg tablet, 84

11013P	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1		..	..	3435.42	Adempas [BN]

riociguat 2.5 mg tablet, 42

11002C	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1		..	..	1717.71	Adempas [BN]

riociguat 2.5 mg tablet, 84

11019Y	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1		..	..	3435.42	Adempas [BN]

riociguat 500 microgram tablet, 84

10995Q	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1		..	..	3435.42	Adempas [BN]

■ RIOCIQUAT

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 1 month following cessation of therapy, as recommended by the TGA-approved Product Information.

Note Special Pricing Arrangements apply.

Authority required

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have WHO Functional Class II, III or IV CTEPH, **AND**
- The condition must be inoperable by pulmonary endarterectomy; OR
- The condition must be recurrent or persistent following pulmonary endarterectomy, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated in a centre with expertise in the management of CTEPH.

CTEPH that is inoperable by pulmonary endarterectomy is defined as follows:

- Right heart catheterisation (RHC) demonstrating pulmonary vascular resistance (PVR) of greater than 300 dyn*sec*cm⁻⁵ measured at least 90 days after start of full anticoagulation; and

- A mean pulmonary artery pressure (PAPmean) of greater than 25 mmHg at least 90 days after start of full anticoagulation.
- CTEPH that is recurrent or persistent subsequent to pulmonary endarterectomy is defined as follows:
- RHC demonstrating a PVR of greater than 300 dyn*sec*cm⁵ measured at least 180 days following pulmonary endarterectomy.

Where a RHC cannot be performed due to right ventricular dysfunction, an echocardiogram demonstrating the dysfunction must be provided at the time of application.

Applications for authorisation must be in writing and must include: (1) completed authority prescription forms sufficient for dose titration; and (2) a completed CTEPH PBS Initial Authority Application - Supporting Information form which includes results from the 3 tests below, to establish baseline measurements, where available: (i) RHC composite assessment, and (ii) ECHO composite assessment, and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgment form; and (4) confirmation of evidence of inoperable CTEPH including results of a pulmonary vascular resistance (PVR), a mean pulmonary artery pressure (PAPmean) and the starting date of full anticoagulation; or (5) confirmation of evidence of recurrent or persistent CTEPH including result of PVR and the date that pulmonary endarterectomy was performed; or (6) confirmation of an echocardiogram demonstrating right ventricular dysfunction.

Where it is not possible to perform all 3 tests above on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only.

In circumstance where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Prescriptions for dose titration must provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment. The quantity approved must be based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 3 repeats.

The assessment of the patient's response to the initial 20-week course of treatment should be made following the preceding 16 weeks of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

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

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must demonstrate stable or responding disease, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated in a centre with expertise in the management of CTEPH.

Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed CTEPH PBS Continuing Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In

all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to this drug is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease.

The assessment of the patient's response to the continuing 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

The maximum quantity per prescription must be based on the dosage recommendations in the TGA-approved Product Information and be limited to provide sufficient supply for 1 month of treatment.

A maximum of 5 repeats will be authorised.

Applications for continuing treatment with this drug should be made two weeks prior to the completion of the 6-month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate disease stability or improvement to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

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

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this agent under the Initial treatment restriction to complete a maximum of 20 weeks of treatment; OR
- Patient must have received insufficient therapy with this agent under the Continuing treatment restriction to complete a maximum of 24 weeks of treatment; OR
- Patient must have received insufficient therapy with this agent under the Grandfathering restriction to complete a maximum of 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 20 or 24 weeks of treatment available under the above respective restriction, **AND**
- The treatment must be the sole PBS-subsidised agent for this condition.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated in a centre with expertise in the management of CTEPH.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Authority required

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Grandfathered patients

Clinical criteria:

- Patient must have previously received treatment with this drug for this condition prior to 1 January 2017, **AND**
- Patient must have a documented history of WHO Functional Class II, III or IV CTEPH, **AND**
- The condition must be inoperable by pulmonary endarterectomy; OR
- The condition must be recurrent or persistent following pulmonary endarterectomy, **AND**
- The treatment must be the sole PBS-subsidised agent for this condition.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated in a centre with expertise in the management of CTEPH.
- CTEPH that is inoperable by pulmonary endarterectomy is defined as follows:

- Right heart catheterisation (RHC) demonstrating pulmonary vascular resistance (PVR) of greater than 300 dyn*sec*cm⁻⁵ measured at least 90 days after start of full anticoagulation; and
- A mean pulmonary artery pressure (PAPmean) of greater than 25 mmHg at least 90 days after start of full anticoagulation.

CTEPH that is recurrent or persistent subsequent to pulmonary endarterectomy is defined as follows:

- RHC demonstrating a PVR of greater than 300 dyn*sec*cm⁵ measured at least 180 days following pulmonary endarterectomy.

Where a RHC cannot be performed due to right ventricular dysfunction, an echocardiogram demonstrating the dysfunction must be provided at the time of application.

Applications for authorisation must be in writing and must include: (1) A completed authority prescription form; and (2) a completed CTEPH PBS Initial Authority Application - Supporting Information form which includes results from the 3 tests below, to establish baseline measurements, where available: (i) RHC composite assessment, and (ii) ECHO composite assessment, and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgment form; and (4) confirmation of evidence of inoperable CTEPH including results of a pulmonary vascular resistance (PVR), a mean pulmonary artery pressure (PAPmean) and the starting date of full anticoagulation; or (5) confirmation of evidence of recurrent or persistent CTEPH including result of PVR and the date that pulmonary endarterectomy was performed; or (6) confirmation of an echocardiogram demonstrating right ventricular dysfunction.

Where it is not possible to perform all 3 tests above on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only.

In circumstance where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

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

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

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

riociguat 500 microgram tablet, 42

11001B	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1717.71	Adempas [BN]	

Botulinum Toxin Program

▪ BOTULINUM TOXIN TYPE A

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Authority required (STREAMLINED)

5221

Blepharospasm or hemifacial spasm

Clinical criteria:

- Patient must have blepharospasm; OR
- Patient must have hemifacial spasm.

Population criteria:

- Patient must be aged 12 years or older.

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by an ophthalmologist; OR
- Must be treated by an otolaryngology head and neck surgeon; OR
- Must be treated by a plastic surgeon.

botulinum toxin type A 100 units injection, 1 vial

10997T	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4		..	..	*1625.94	38.80	Botox [AG]

▪ BOTULINUM TOXIN TYPE A

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Authority required (STREAMLINED)

5406

Spasmodic torticollis

Clinical criteria:

- Patient must have spasmodic torticollis, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be as adjunctive therapy to current standard care.

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by a plastic surgeon; OR
- Must be treated by a rehabilitation specialist.

botulinum toxin type A 100 units injection, 1 vial

11023E	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4		..	..	*1625.94	38.80	Botox [AG]

▪ BOTULINUM TOXIN TYPE A

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

5409

Urinary incontinence

Clinical criteria:

- The condition must be due to neurogenic detrusor overactivity, as demonstrated by urodynamic study, **AND**
- The condition must be inadequately controlled by anti-cholinergic therapy, **AND**

- Patient must experience at least 14 episodes of urinary incontinence per week prior to commencement of treatment with Botulinum Toxin Type A Neurotoxin Complex, **AND**
- Patient must be willing and able to self-catheterise, **AND**
- The treatment must not continue if the patient does not achieve a 50% or greater reduction from baseline in urinary incontinence episodes 6-12 weeks after the first treatment, **AND**
- Patient must have multiple sclerosis; OR
- Patient must have a spinal cord injury; OR
- Patient must be aged 18 years or older and have spina bifida.

Treatment criteria:

- Must be treated by a urologist; OR
- Must be treated by a urogynaecologist.

botulinum toxin type A 100 units injection, 1 vial

10993N	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	..	*1625.94	38.80	Botox [AG]

▪ **BOTULINUM TOXIN TYPE A**

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Authority required (STREAMLINED)

5359

Dynamic equinus foot deformity

Clinical criteria:

- The condition must be due to spasticity, **AND**
- Patient must have cerebral palsy, **AND**
- Patient must be ambulant.

Population criteria:

- Patient must be aged from 2 to 17 years inclusive.

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist.

Authority required (STREAMLINED)

5407

Dynamic equinus foot deformity

Clinical criteria:

- The condition must be due to spasticity, **AND**
- Patient must have cerebral palsy, **AND**
- Patient must be ambulant, **AND**
- Patient must have commenced PBS-subsidised treatment with Botulinum Toxin Type A Purified Neurotoxin Complex as a paediatric patient.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist.

botulinum toxin type A 100 units injection, 1 vial

10998W	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	..	*1625.94	38.80	Botox [AG]

▪ **BOTULINUM TOXIN TYPE A**

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

5262

Chronic migraine

Clinical criteria:

- Patient must have experienced an average of 15 or more headache days per month, with at least 8 days of migraine, over a period of at least 6 months, prior to commencement of treatment with botulinum toxin type A neurotoxin, **AND**
- Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with botulinum toxin type A neurotoxin, **AND**

- Patient must have achieved and maintained a 50% or greater reduction from baseline in the number of headache days per month after two treatment cycles (each of 12 weeks duration) in order to be eligible for continuing PBS-subsidised treatment, **AND**
- Patient must be appropriately managed by his or her practitioner for medication overuse headache, prior to initiation of treatment with botulinum toxin.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a neurologist.
- Prophylactic migraine medications are propranolol, amitriptylin, methsergide, pizotifen, cyproheptadine or topiramate.

botulinum toxin type A 100 units injection, 1 vial

11000Y	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	..	*1625.94	38.80	Botox [AG]

▪ **BOTULINUM TOXIN TYPE A**

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

5333

Urinary incontinence

Clinical criteria:

- The condition must be due to idiopathic overactive bladder, **AND**
- The condition must have been inadequately controlled by therapy involving at least two alternative anti-cholinergic agents, **AND**
- Patient must experience at least 14 episodes of urinary incontinence per week prior to commencement of treatment with botulinum toxin type A neurotoxin complex, **AND**
- Patient must be willing and able to self-catheterise, **AND**
- The treatment must not continue if the patient does not achieve a 50% or greater reduction from baseline in urinary incontinence episodes 6-12 weeks after the first treatment.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a urologist; OR
- Must be treated by a urogynaecologist.

botulinum toxin type A 100 units injection, 1 vial

11004E	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	..	*1625.94	38.80	Botox [AG]

▪ **BOTULINUM TOXIN TYPE A**

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

5408

Severe primary axillary hyperhidrosis

Clinical criteria:

- Patient must have previously failed topical aluminium chloride hexahydrate after one to two months of treatment; OR
- Patient must be intolerant to topical aluminium chloride hexahydrate treatment.

Population criteria:

- Patient must be aged 12 years or older.

Treatment criteria:

- Must be treated by a dermatologist; OR
- Must be treated by a neurologist; OR
- Must be treated by a paediatrician.

Maximum number of treatments per year is 3, with no less than 4 months to elapse between treatments.

botulinum toxin type A 100 units injection, 1 vial

11016T	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	..	*1625.94	38.80	Botox [AG]

▪ **BOTULINUM TOXIN TYPE A**

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Authority required (STREAMLINED)

5178

Moderate to severe spasticity of the upper limb

Clinical criteria:

- Patient must have cerebral palsy.

Population criteria:

- Patient must be aged from 2 to 17 years inclusive.

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist; OR
- Must be treated by a plastic surgeon.

Authority required (STREAMLINED)**5261**

Moderate to severe spasticity of the upper limb

Clinical criteria:

- Patient must have cerebral palsy, **AND**
- Patient must have commenced PBS-subsidised treatment with Botulinum Type A Neurotoxin Complex as a paediatric patient.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist; OR
- Must be treated by a plastic surgeon.

Note Contact the Department of Human Services before commencing PBS-subsidised treatment in cerebral palsy patients who have been treated for moderate to severe spasticity of the upper limb with non-PBS-subsidised botulinum toxin prior to the age of 18.

Authority required (STREAMLINED)**5220**

Moderate to severe spasticity of the upper limb following a stroke

Clinical criteria:

- The condition must be moderate to severe spasticity of the upper limb/s following stroke, defined as a Modified Ashworth Scale rating of 3 or more, **AND**
- The treatment must not be initiated until three months post-stroke, **AND**
- The treatment must only be used as second line therapy when standard management has failed; OR
- The treatment must only be used as an adjunct to physical therapy, **AND**
- The treatment must not continue if the patient does not respond (defined as not having had a decrease in spasticity rating greater than 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (total Botox, Dysport, and Xeomin), **AND**
- The treatment must not exceed 4 treatment periods (total Botox, Dysport, and Xeomin) per upper limb per lifetime, **AND**
- Patient must not have established severe contracture in the limb to be treated.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a rehabilitation specialist; OR
- Must be treated by a plastic surgeon; OR
- Must be treated by a geriatrician.

The date of the stroke must be documented in the patient's medical records when treatment is initiated.

Standard management includes physiotherapy and/or oral spasticity agents.

botulinum toxin type A 100 units injection, 1 vial

10999X	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..		*1625.94	38.80	Botox [AG]

■ CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Authority required (STREAMLINED)**5220**

Moderate to severe spasticity of the upper limb following a stroke

Clinical criteria:

- The condition must be moderate to severe spasticity of the upper limb/s following stroke, defined as a Modified Ashworth Scale rating of 3 or more, **AND**
- The treatment must not be initiated until three months post-stroke, **AND**
- The treatment must only be used as second line therapy when standard management has failed; OR
- The treatment must only be used as an adjunct to physical therapy, **AND**
- The treatment must not continue if the patient does not respond (defined as not having had a decrease in spasticity rating greater than 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (total Botox, Dysport, and Xeomin), **AND**
- The treatment must not exceed 4 treatment periods (total Botox, Dysport, and Xeomin) per upper limb per lifetime, **AND**
- Patient must not have established severe contracture in the limb to be treated.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a rehabilitation specialist; OR
- Must be treated by a plastic surgeon; OR
- Must be treated by a geriatrician.

The date of the stroke must be documented in the patient's medical records when treatment is initiated.

Standard management includes physiotherapy and/or oral spasticity agents.

clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 vial

10982B	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	..	*1420.78	38.80	Dysport [IS]

clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 vial

10988H	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	..	*1272.16	38.80	Dysport [IS]

■ CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Authority required (STREAMLINED)

5405

Blepharospasm or hemifacial spasm

Clinical criteria:

- Patient must have blepharospasm; OR
- Patient must have hemifacial spasm.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by an ophthalmologist; OR
- Must be treated by an otolaryngology head and neck surgeon; OR
- Must be treated by a plastic surgeon.

clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 vial

10987G	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	..	*1420.78	38.80	Dysport [IS]

clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 vial

11022D	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	..	*1272.16	38.80	Dysport [IS]

■ CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Authority required (STREAMLINED)

5406

Spasmodic torticollis

Clinical criteria:

- Patient must have spasmodic torticollis, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be as adjunctive therapy to current standard care.

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by a plastic surgeon; OR

- Must be treated by a rehabilitation specialist.

clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 vial

11007H	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	..	*1420.78	38.80	Dysport [IS]

clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 vial

11015R	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	..	*1272.16	38.80	Dysport [IS]

■ CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Authority required (STREAMLINED)

5359

Dynamic equinus foot deformity

Clinical criteria:

- The condition must be due to spasticity, **AND**
- Patient must have cerebral palsy, **AND**
- Patient must be ambulant.

Population criteria:

- Patient must be aged from 2 to 17 years inclusive.

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist.

Authority required (STREAMLINED)

5332

Dynamic equinus foot deformity

Clinical criteria:

- The condition must be due to spasticity, **AND**
- Patient must be an ambulant cerebral palsy patient, **AND**
- Patient must have commenced on PBS-subsidised treatment with clostridium botulinum type A toxin-haemagglutinin complex as a paediatric patient.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist.

clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 vial

10981Y	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	..	*1420.78	38.80	Dysport [IS]

clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 vial

11006G	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	..	*1272.16	38.80	Dysport [IS]

■ INCOBOTULINUM TOXINA

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Authority required (STREAMLINED)

5220

Moderate to severe spasticity of the upper limb following a stroke

Clinical criteria:

- The condition must be moderate to severe spasticity of the upper limb/s following stroke, defined as a Modified Ashworth Scale rating of 3 or more, **AND**
- The treatment must not be initiated until three months post-stroke, **AND**
- The treatment must only be used as second line therapy when standard management has failed; OR
- The treatment must only be used as an adjunct to physical therapy, **AND**
- The treatment must not continue if the patient does not respond (defined as not having had a decrease in spasticity rating greater than 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (total Botox, Dysport, and Xeomin), **AND**

- The treatment must not exceed 4 treatment periods (total Botox, Dysport, and Xeomin) per upper limb per lifetime, **AND**
- Patient must not have established severe contracture in the limb to be treated.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a rehabilitation specialist; OR
- Must be treated by a plastic surgeon; OR
- Must be treated by a geriatrician.

The date of the stroke must be documented in the patient's medical records when treatment is initiated.

Standard management includes physiotherapy and/or oral spasticity agents.

incobotulinumtoxinA 100 mouse LD50 units injection, 1 x 100 mouse LD50 units vial

10983C	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4		..	..	*1547.02	38.80	Xeomin [EZ]

▪ **INCOBOTULINUM TOXINA**

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Authority required (STREAMLINED)

5360

Blepharospasm

Clinical criteria:

- Patient must have blepharospasm.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by an ophthalmologist; OR
- Must be treated by an otolaryngology head and neck surgeon; OR
- Must be treated by a plastic surgeon.

incobotulinumtoxinA 100 mouse LD50 units injection, 1 x 100 mouse LD50 units vial

10994P	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4		..	..	*1547.02	38.80	Xeomin [EZ]

▪ **INCOBOTULINUM TOXINA**

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Authority required (STREAMLINED)

5222

Spasmodic torticollis

Clinical criteria:

- Patient must have spasmodic torticollis, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be as adjunctive therapy to current standard care.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by a plastic surgeon; OR
- Must be treated by a rehabilitation specialist.

incobotulinumtoxinA 100 mouse LD50 units injection, 1 x 100 mouse LD50 units vial

11005F	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4		..	..	*1547.02	38.80	Xeomin [EZ]