



Australian Government

Department of Health



Schedule of Pharmaceutical Benefits

Summary of Changes

Effective 1 February 2016



Fees, Patient Contributions and Safety Net Thresholds

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

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

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

Summary of Changes

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

General Pharmaceutical Benefits

Additions

Addition – Item

- 10605E **FLUCLOXACILLIN**, flucloxacillin 1 g injection, 10 x 1 g vials (*Hospira Pty Limited*)
- 10609J **FLUCLOXACILLIN**, flucloxacillin 1 g injection, 10 x 1 g vials (*Hospira Pty Limited*) (**Dental**)
- 10614P **RUXOLITINIB**, ruxolitinib 5 mg tablet, 56 (*Jakavi*)
- 10616R **RUXOLITINIB**, ruxolitinib 5 mg tablet, 56 (*Jakavi*)
- 10615Q **RUXOLITINIB**, ruxolitinib 15 mg tablet, 56 (*Jakavi*)
- 10619X **RUXOLITINIB**, ruxolitinib 15 mg tablet, 56 (*Jakavi*)
- 10617T **RUXOLITINIB**, ruxolitinib 20 mg tablet, 56 (*Jakavi*)
- 10618W **RUXOLITINIB**, ruxolitinib 20 mg tablet, 56 (*Jakavi*)

Addition – Brand

- 9012H *APO-Alendronate Plus D3 70 mg/70 mcg, TX* – **ALENDRONATE + COLECALCIFEROL**, alendronate 70 mg + colecalciferol 70 microgram tablet, 4
- 9012H *Chem mart Alendronate Plus D3 70 mg/70 mcg, CH* – **ALENDRONATE + COLECALCIFEROL**, alendronate 70 mg + colecalciferol 70 microgram tablet, 4
- 9012H *Terry White Chemists Alendronate Plus D3 70 mg/70 mcg, TW* – **ALENDRONATE + COLECALCIFEROL**, alendronate 70 mg + colecalciferol 70 microgram tablet, 4
- 9183H *APO-Alendronate Plus D3 70 mg/140 mcg, TX* – **ALENDRONATE + COLECALCIFEROL**, alendronate 70 mg + colecalciferol 140 microgram tablet, 4
- 9183H *Chem mart Alendronate Plus D3 70 mg/140 mcg, CH* – **ALENDRONATE + COLECALCIFEROL**, alendronate 70 mg + colecalciferol 140 microgram tablet, 4
- 9183H *Terry White Chemists Alendronate Plus D3 70 mg/140 mcg, TW* – **ALENDRONATE + COLECALCIFEROL**, alendronate 70 mg + colecalciferol 140 microgram tablet, 4
- 2417F *Amitriptyline Alphapharm 10, AL* – **AMITRIPTYLINE**, amitriptyline hydrochloride 10 mg tablet, 50
- 2418G *Amitriptyline Alphapharm 25, AL* – **AMITRIPTYLINE**, amitriptyline hydrochloride 25 mg tablet, 50
- 2429W *Amitriptyline Alphapharm 50, AL* – **AMITRIPTYLINE**, amitriptyline hydrochloride 50 mg tablet, 50
- 10295W *Esomeprazole AN, EA* – **ESOMEPRAZOLE**, esomeprazole 20 mg capsule, 30
- 10343J *Esomeprazole AN, EA* – **ESOMEPRAZOLE**, esomeprazole 20 mg capsule, 30
- 10330Q *Esomeprazole AN, EA* – **ESOMEPRAZOLE**, esomeprazole 40 mg capsule, 30
- 10331R *Esomeprazole AN, EA* – **ESOMEPRAZOLE**, esomeprazole 40 mg capsule, 30
- 1554T *Arrow Pharma Pty Ltd, RW* – **ISONIAZID**, isoniazid 100 mg tablet, 100

1653B	<i>Morphine MR AN, EA</i> – MORPHINE , morphine sulfate 10 mg tablet: modified release, 28 tablets
1654C	<i>Morphine MR AN, EA</i> – MORPHINE , morphine sulfate 30 mg tablet: modified release, 28 tablets
1655D	<i>Morphine MR AN, EA</i> – MORPHINE , morphine sulfate 60 mg tablet: modified release, 28 tablets
1656E	<i>Morphine MR AN, EA</i> – MORPHINE , morphine sulfate 100 mg tablet: modified release, 28 tablets
1850J	<i>Phenobarbitone Aspen, RW</i> – PHENOBARBITONE , phenobarbitone 30 mg tablet, 200
8694N	<i>Actaze, RW</i> – PIOGLITAZONE , pioglitazone 15 mg tablet, 28
8695P	<i>Actaze, RW</i> – PIOGLITAZONE , pioglitazone 30 mg tablet, 28
8696Q	<i>Actaze, RW</i> – PIOGLITAZONE , pioglitazone 45 mg tablet, 28
10551H	<i>Rizatriptan ODT GH, GQ</i> – RIZATRIPTAN , rizatriptan 10 mg tablet: orally disintegrating, 2
8646C	<i>TACROLIMUS APOTEX, TX</i> – TACROLIMUS , tacrolimus 500 microgram capsule, 100
8647D	<i>TACROLIMUS APOTEX, TX</i> – TACROLIMUS , tacrolimus 1 mg capsule, 100
8648E	<i>TACROLIMUS APOTEX, TX</i> – TACROLIMUS , tacrolimus 5 mg capsule, 50
10173K	<i>Voriconazole Sandoz, SZ</i> – VORICONAZOLE , voriconazole 50 mg tablet, 56
9363T	<i>Voriconazole Sandoz, SZ</i> – VORICONAZOLE , voriconazole 50 mg tablet, 56
10198R	<i>Voriconazole Sandoz, SZ</i> – VORICONAZOLE , voriconazole 200 mg tablet, 56
9364W	<i>Voriconazole Sandoz, SZ</i> – VORICONAZOLE , voriconazole 200 mg tablet, 56

Addition – Equivalence Indicator

10173K	<i>Vfend, PF</i> – VORICONAZOLE , voriconazole 50 mg tablet, 56
9363T	<i>Vfend, PF</i> – VORICONAZOLE , voriconazole 50 mg tablet, 56
10198R	<i>Vfend, PF</i> – VORICONAZOLE , voriconazole 200 mg tablet, 56
9364W	<i>Vfend, PF</i> – VORICONAZOLE , voriconazole 200 mg tablet, 56

Deletions

Deletion – Brand

2655R	<i>GenRx Cephalexin, GX</i> – CEPHALEXIN , cephalexin 250 mg capsule, 20
3058Y	<i>GenRx Cephalexin, GX</i> – CEPHALEXIN , cephalexin 250 mg capsule, 20
3317N	<i>GenRx Cephalexin, GX</i> – CEPHALEXIN , cephalexin 250 mg capsule, 20 (Dental)
3119E	<i>GenRx Cephalexin, GX</i> – CEPHALEXIN , cephalexin 500 mg capsule, 20
3318P	<i>GenRx Cephalexin, GX</i> – CEPHALEXIN , cephalexin 500 mg capsule, 20 (Dental)
1370D	<i>Auspril, QA</i> – ENALAPRIL , enalapril maleate 5 mg tablet, 30
1368B	<i>Auspril, QA</i> – ENALAPRIL , enalapril maleate 10 mg tablet, 30
1369C	<i>Auspril, QA</i> – ENALAPRIL , enalapril maleate 20 mg tablet, 30
8246B	<i>Karbesat 75, QA</i> – IRBESARTAN , irbesartan 75 mg tablet, 30
8247C	<i>Karbesat 150, QA</i> – IRBESARTAN , irbesartan 150 mg tablet, 30
8248D	<i>Karbesat 300, QA</i> – IRBESARTAN , irbesartan 300 mg tablet, 30
1554T	<i>Fawns and McAllan Proprietary Limited, FM</i> – ISONIAZID , isoniazid 100 mg tablet, 100
8063J	<i>Seaze 5, QA</i> – LAMOTRIGINE , lamotrigine 5 mg tablet, 56
2848X	<i>Seaze 25, QA</i> – LAMOTRIGINE , lamotrigine 25 mg tablet, 56
2849Y	<i>Seaze 50, QA</i> – LAMOTRIGINE , lamotrigine 50 mg tablet, 56
2850B	<i>Seaze 100, QA</i> – LAMOTRIGINE , lamotrigine 100 mg tablet, 56
2851C	<i>Seaze 200, QA</i> – LAMOTRIGINE , lamotrigine 200 mg tablet, 56
8654L	<i>Levitam 250, QA</i> – LEVETIRACETAM , levetiracetam 250 mg tablet, 60

8655M	<i>Levitam 500, QA</i> – LEVETIRACETAM , levetiracetam 500 mg tablet, 60
8656N	<i>Levitam 1000, QA</i> – LEVETIRACETAM , levetiracetam 1 g tablet, 60
8627C	<i>Montelukast RBX, RA</i> – MONTELUKAST , montelukast 4 mg tablet: chewable, 28
8628D	<i>Montelukast RBX, RA</i> – MONTELUKAST , montelukast 5 mg tablet: chewable, 28
1850J	<i>Aspen Pharma Pty Ltd, QA</i> – PHENOBARBITONE , phenobarbitone 30 mg tablet, 200
8457D	<i>Seronia 100, QA</i> – QUETIAPINE , quetiapine 100 mg tablet, 90
8458E	<i>Seronia 200, QA</i> – QUETIAPINE , quetiapine 200 mg tablet, 60
8580N	<i>Seronia 300, QA</i> – QUETIAPINE , quetiapine 300 mg tablet, 60

Alterations

Changes to Restrictions

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

1842Y	RISPERIDONE , risperidone 500 microgram tablet, 20 (<i>APO-Risperidone, Risperdal</i>)
1846E	RISPERIDONE , risperidone 500 microgram tablet, 20 (<i>APO-Risperidone, Risperdal</i>)
3169T	RISPERIDONE , risperidone 1 mg tablet, 60 (<i>APO-Risperidone, Ozidal, Risper, Risperdal, Rispericor 1, Risperidone AN, Risperidone Actavis 1, Risperidone Sandoz, Risperidone generichealth, Risperidone-DRLA, Risperidone-GA, Rispernia, Rixadone</i>)
3170W	RISPERIDONE , risperidone 2 mg tablet, 60 (<i>APO-Risperidone, Ozidal, Risper, Risperdal, Rispericor 2, Risperidone AN, Risperidone Actavis 2, Risperidone Sandoz, Risperidone generichealth, Risperidone-DRLA, Risperidone-GA, Rispernia, Rixadone</i>)
3171X	RISPERIDONE , risperidone 3 mg tablet, 60 (<i>APO-Risperidone, Ozidal, Risper, Risperdal, Rispericor 3, Risperidone AN, Risperidone Actavis 3, Risperidone Sandoz, Risperidone generichealth, Risperidone-DRLA, Risperidone-GA, Rispernia, Rixadone</i>)
3172Y	RISPERIDONE , risperidone 4 mg tablet, 60 (<i>APO-Risperidone, Ozidal, Risper, Risperdal, Rispericor 4, Risperidone AN, Risperidone Sandoz, Risperidone generichealth, Risperidone-DRLA, Risperidone-GA, Rispernia, Rixadone</i>)
8100H	RISPERIDONE , risperidone 1 mg/mL oral liquid, 100 mL (<i>Risperdal</i>)
8780D	RISPERIDONE , risperidone 25 mg injection: modified release [1 x 25 mg vial] (& inert substance diluent [1 x 2 mL syringe], 1 pack (<i>Risperdal Consta</i>)
8781E	RISPERIDONE , risperidone 37.5 mg injection: modified release [1 x 37.5 mg vial] (& inert substance diluent [1 x 2 mL syringe], 1 pack (<i>Risperdal Consta</i>)
8782F	RISPERIDONE , risperidone 50 mg injection: modified release [1 x 50 mg vial] (& inert substance diluent [1 x 2 mL syringe], 1 pack (<i>Risperdal Consta</i>)
8787L	RISPERIDONE , risperidone 500 microgram tablet, 60 (<i>Ozidal, Risper, Rispericor 0.5, Risperidone AN, Risperidone Actavis 0.5, Risperidone GH, Risperidone Sandoz, Risperidone-DRLA, Risperidone-GA, Rispernia, Rixadone</i>)
8788M	RISPERIDONE , risperidone 500 microgram tablet: orally disintegrating, 28 (<i>Risperdal Quicklet</i>)
8789N	RISPERIDONE , risperidone 1 mg tablet, 60 (<i>APO-Risperidone, Ozidal, Risper, Risperdal, Rispericor 1, Risperidone AN, Risperidone Actavis 1, Risperidone Sandoz, Risperidone generichealth, Risperidone-DRLA, Risperidone-GA, Rispernia, Rixadone</i>)
8790P	RISPERIDONE , risperidone 1 mg tablet: orally disintegrating, 28 (<i>Risperdal Quicklet</i>)
8792R	RISPERIDONE , risperidone 1 mg tablet: orally disintegrating, 28 (<i>Risperdal Quicklet</i>)
8794W	RISPERIDONE , risperidone 2 mg tablet: orally disintegrating, 28 (<i>Risperdal Quicklet</i>)
8869T	RISPERIDONE , risperidone 500 microgram tablet, 60 (<i>Ozidal, Risper, Rispericor 0.5, Risperidone AN, Risperidone Actavis 0.5, Risperidone GH, Risperidone Sandoz, Risperidone-DRLA, Risperidone-GA, Rispernia, Rixadone</i>)
8870W	RISPERIDONE , risperidone 500 microgram tablet: orally disintegrating, 28 (<i>Risperdal Quicklet</i>)
9075P	RISPERIDONE , risperidone 3 mg tablet: orally disintegrating, 28 (<i>Risperdal Quicklet</i>)
9076Q	RISPERIDONE , risperidone 4 mg tablet: orally disintegrating, 28 (<i>Risperdal Quicklet</i>)

9079W	RISPERIDONE , risperidone 2 mg tablet, 60 (<i>APO-Risperidone, Ozidal, Rispa, Risperdal, Rispericor 2, Risperidone AN, Risperidone Actavis 2, Risperidone Sandoz, Risperidone generichealth, Risperidone-DRLA, Risperidone-GA, Rispermia, Rixadone</i>)
9080X	RISPERIDONE , risperidone 2 mg tablet: orally disintegrating, 28 (<i>Risperdal Quicklet</i>)
9293D	RISPERIDONE , risperidone 1 mg/mL oral liquid, 100 mL (<i>Risperdal</i>)
10125X	TICARCILLIN + CLAVULANIC ACID , ticarcillin 3 g + clavulanic acid 100 mg injection, 1 x 3.1 g vial (<i>Timentin</i>)(Dental)
2444P	TRANLYCYPROMINE , tranlycypromine 10 mg tablet, 50 (<i>Parnate</i>)
2209G	WARFARIN , warfarin sodium 2 mg tablet, 50 (<i>Coumadin</i>)
2211J	WARFARIN , warfarin sodium 5 mg tablet, 50 (<i>Coumadin, Marevan</i>)
2843P	WARFARIN , warfarin sodium 1 mg tablet, 50 (<i>Coumadin, Marevan</i>)
2844Q	WARFARIN , warfarin sodium 3 mg tablet, 50 (<i>Marevan</i>)

Alteration – Manufacturer Code

		<i>From</i>	<i>To</i>
1004W	<i>Diamox</i> – ACETAZOLAMIDE , acetazolamide 250 mg tablet, 100	QA	RW
8511Y	<i>Alendro Once Weekly</i> – ALENDRONATE , alendronate 70 mg tablet, 4	QA	RW
2600W	<i>Allosig</i> – ALLOPURINOL , allopurinol 100 mg tablet, 200	FM	RF
2600W	<i>Zyloprim</i> – ALLOPURINOL , allopurinol 100 mg tablet, 200	QA	RW
2604C	<i>Allosig</i> – ALLOPURINOL , allopurinol 300 mg tablet, 60	FM	RF
2604C	<i>Zyloprim</i> – ALLOPURINOL , allopurinol 300 mg tablet, 60	QA	RW
2751T	<i>Amlor 5</i> – AMLODIPINE , amlodipine 5 mg tablet, 30	QA	RW
2752W	<i>Amlor 10</i> – AMLODIPINE , amlodipine 10 mg tablet, 30	QA	RW
1886G	<i>Bgramin</i> – AMOXYCILLIN , amoxicillin 125 mg/5 mL oral liquid: powder for, 100 mL	GN	FM
3302T	<i>Bgramin</i> – AMOXYCILLIN , amoxicillin 125 mg/5 mL oral liquid: powder for, 100 mL (Dental)	GN	FM
1887H	<i>Bgramin</i> – AMOXYCILLIN , amoxicillin 250 mg/5 mL oral liquid: powder for, 100 mL	GN	FM
3393N	<i>Bgramin</i> – AMOXYCILLIN , amoxicillin 250 mg/5 mL oral liquid: powder for, 100 mL (Dental)	GN	FM
2729P	<i>Stelax 10</i> – BACLOFEN , baclofen 10 mg tablet, 100	QA	RW
2730Q	<i>Stelax 25</i> – BACLOFEN , baclofen 25 mg tablet, 100	QA	RW
1109J	<i>Artane</i> – BENZHEXOL , benzhexol hydrochloride 2 mg tablet, 200	QA	RW
1110K	<i>Artane</i> – BENZHEXOL , benzhexol hydrochloride 5 mg tablet, 200	QA	RW
8604W	<i>Bicard 2.5</i> – BISOPROLOL , bisoprolol fumarate 2.5 mg tablet, 28	QA	RW
8605X	<i>Bicard 5</i> – BISOPROLOL , bisoprolol fumarate 5 mg tablet, 28	QA	RW
8606Y	<i>Bicard 10</i> – BISOPROLOL , bisoprolol fumarate 10 mg tablet, 28	QA	RW
8760C	<i>Capoten</i> – CAPTOPRIL , captopril 5 mg/mL oral liquid, 95 mL	QA	RW
1148K	<i>Capoten</i> – CAPTOPRIL , captopril 25 mg tablet, 90	QA	RW
1149L	<i>Capoten</i> – CAPTOPRIL , captopril 50 mg tablet, 90	QA	RW
1208N	<i>Ciprol 250</i> – CIPROFLOXACIN , ciprofloxacin 250 mg tablet, 14	QA	RW
1209P	<i>Ciprol 500</i> – CIPROFLOXACIN , ciprofloxacin 500 mg tablet, 14	QA	RW
1210Q	<i>Ciprol 750</i> – CIPROFLOXACIN , ciprofloxacin 750 mg tablet, 14	QA	RW
8220P	<i>Talam</i> – CITALOPRAM , citalopram 20 mg tablet, 28	QA	RW
8318T	<i>Clarithro 250</i> – CLARITHROMYCIN , clarithromycin 250 mg tablet, 14	QA	RW
3161J	<i>Valpam 2</i> – DIAZEPAM , diazepam 2 mg tablet, 50	QA	RW
5071X	<i>Valpam 2</i> – DIAZEPAM , diazepam 2 mg tablet, 50 (Dental)	QA	RW

3162K	Valpam 5 – DIAZEPAM , diazepam 5 mg tablet, 50	QA	RW
5072Y	Valpam 5 – DIAZEPAM , diazepam 5 mg tablet, 50 (Dental)	QA	RW
2532G	Aridon 5 – DONEPEZIL , donepezil hydrochloride 5 mg tablet, 28	QA	RW
8495D	Aridon 5 – DONEPEZIL , donepezil hydrochloride 5 mg tablet, 28	QA	RW
2479L	Aridon 10 – DONEPEZIL , donepezil hydrochloride 10 mg tablet, 28	QA	RW
8496E	Aridon 10 – DONEPEZIL , donepezil hydrochloride 10 mg tablet, 28	QA	RW
2702F	Doxsig – DOXYCYCLINE , doxycycline 100 mg tablet, 7	QA	RW
2709N	Doxsig – DOXYCYCLINE , doxycycline 100 mg tablet, 7	QA	RW
2714W	Doxsig – DOXYCYCLINE , doxycycline 100 mg tablet, 7	QA	RW
3321T	Doxsig – DOXYCYCLINE , doxycycline 100 mg tablet, 7 (Dental)	QA	RW
1370D	Malean – ENALAPRIL , enalapril maleate 5 mg tablet, 30	FM	RW
1368B	Malean – ENALAPRIL , enalapril maleate 10 mg tablet, 30	FM	RW
1369C	Malean – ENALAPRIL , enalapril maleate 20 mg tablet, 30	FM	RW
8700X	Lexam 10 – ESCITALOPRAM , escitalopram 10 mg tablet, 28	QA	RW
8701Y	Lexam 20 – ESCITALOPRAM , escitalopram 20 mg tablet, 28	QA	RW
8092X	Favic 125 – FAMCICLOVIR , famciclovir 125 mg tablet, 40	QA	RW
2274Q	Favic 250 – FAMCICLOVIR , famciclovir 250 mg tablet, 20	QA	RW
8002E	Favic 250 – FAMCICLOVIR , famciclovir 250 mg tablet, 21	QA	RW
8217L	Favic 250 – FAMCICLOVIR , famciclovir 250 mg tablet, 56	QA	RW
8896F	Favic 500 – FAMCICLOVIR , famciclovir 500 mg tablet, 56	QA	RW
8897G	Favic 500 – FAMCICLOVIR , famciclovir 500 mg tablet, 30	QA	RW
2487X	Ausfam 20 – FAMOTIDINE , famotidine 20 mg tablet, 60	QA	RW
2488Y	Ausfam 40 – FAMOTIDINE , famotidine 40 mg tablet, 30	QA	RW
2366M	Felodil XR 5 – FELODIPINE , felodipine 5 mg tablet: modified release, 30 tablets	QA	RW
2367N	Felodil XR 10 – FELODIPINE , felodipine 10 mg tablet: modified release, 30 tablets	QA	RW
1475P	Fluzole 200 – FLUCONAZOLE , fluconazole 200 mg capsule, 28	QA	RW
1434L	Auscap Aspen – FLUOXETINE , fluoxetine 20 mg capsule, 28	QA	RW
1182F	Fosipril 10 – FOSINOPRIL , fosinopril sodium 10 mg tablet, 30	QA	RW
1183G	Fosipril 20 – FOSINOPRIL , fosinopril sodium 20 mg tablet, 30	QA	RW
1810G	Urex-M – FRUSEMIDE , frusemide 20 mg tablet, 50	FM	RW
2412Y	Urex – FRUSEMIDE , frusemide 40 mg tablet, 100	FM	RW
2415D	Urex-Forte – FRUSEMIDE , frusemide 500 mg tablet, 50	FM	RW
8505P	Gabapentin Aspen 100 – GABAPENTIN , gabapentin 100 mg capsule, 100	FM	RW
1834M	Gabapentin Aspen 300 – GABAPENTIN , gabapentin 300 mg capsule, 100	FM	RW
1835N	Gabapentin Aspen 400 – GABAPENTIN , gabapentin 400 mg capsule, 100	FM	RW
8559L	Gabapentin Aspen 600 – GABAPENTIN , gabapentin 600 mg tablet, 100	FM	RW
8389M	Gabapentin Aspen 800 – GABAPENTIN , gabapentin 800 mg tablet, 100	FM	RW
1453L	Ausgem – GEMFIBROZIL , gemfibrozil 600 mg tablet, 60	QA	RW
9248R	Ausgem – GEMFIBROZIL , gemfibrozil 600 mg tablet, 60	QA	RW
2449X	Nidem – GLICLAZIDE , gliclazide 80 mg tablet, 100	QA	RW
8450R	Diapride 1 – GLIMEPIRIDE , glimepiride 1 mg tablet, 30	QA	RW
8451T	Diapride 2 – GLIMEPIRIDE , glimepiride 2 mg tablet, 30	QA	RW
8533D	Diapride 3 – GLIMEPIRIDE , glimepiride 3 mg tablet, 30	QA	RW
8452W	Diapride 4 – GLIMEPIRIDE , glimepiride 4 mg tablet, 30	QA	RW

1459T	<i>Anginine Stabilised</i> – GLYCERYL TRINITRATE , glyceryl trinitrate 600 microgram tablet: sublingual, 100 tablets	QA	RW
1459T	<i>Lycinate</i> – GLYCERYL TRINITRATE , glyceryl trinitrate 600 microgram tablet: sublingual, 100 tablets	FM	RF
5108W	<i>Anginine Stabilised</i> – GLYCERYL TRINITRATE , glyceryl trinitrate 600 microgram tablet: sublingual, 100 tablets (Dental)	QA	RW
5108W	<i>Lycinate</i> – GLYCERYL TRINITRATE , glyceryl trinitrate 600 microgram tablet: sublingual, 100 tablets (Dental)	FM	RF
1512N	<i>Hequinel</i> – HYDROXYCHLOROQUINE , hydroxychloroquine sulfate 200 mg tablet, 100	QA	RW
8532C	<i>Tenaxil SR</i> – INDAPAMIDE , indapamide hemihydrate 1.5 mg tablet: modified release, 90 tablets	QA	RW
2436F	<i>Insig</i> – INDAPAMIDE , indapamide hemihydrate 2.5 mg tablet, 90	QA	RW
2591J	<i>Rocta 10</i> – ISOTRETINOIN , isotretinoin 10 mg capsule, 60	QA	RW
2592K	<i>Rocta 20</i> – ISOTRETINOIN , isotretinoin 20 mg capsule, 60	QA	RW
8063J	<i>Lamotrigine Aspen 5</i> – LAMOTRIGINE , lamotrigine 5 mg tablet, 56	FM	RW
2848X	<i>Lamotrigine Aspen 25</i> – LAMOTRIGINE , lamotrigine 25 mg tablet, 56	FM	RW
2849Y	<i>Lamotrigine Aspen 50</i> – LAMOTRIGINE , lamotrigine 50 mg tablet, 56	FM	RW
2850B	<i>Lamotrigine Aspen 100</i> – LAMOTRIGINE , lamotrigine 100 mg tablet, 56	FM	RW
2851C	<i>Lamotrigine Aspen 200</i> – LAMOTRIGINE , lamotrigine 200 mg tablet, 56	FM	RW
2456G	<i>Fibsol 5</i> – LISINOPRIL , lisinopril 5 mg tablet, 30	QA	RW
2457H	<i>Fibsol 10</i> – LISINOPRIL , lisinopril 10 mg tablet, 30	QA	RW
2458J	<i>Fibsol 20</i> – LISINOPRIL , lisinopril 20 mg tablet, 30	QA	RW
8887R	<i>Movalis 7.5</i> – MELOXICAM , meloxicam 7.5 mg capsule, 30	QA	RW
8888T	<i>Movalis 15</i> – MELOXICAM , meloxicam 15 mg capsule, 30	QA	RW
8561N	<i>Movalis 7.5</i> – MELOXICAM , meloxicam 7.5 mg tablet, 30	QA	RW
8562P	<i>Movalis 15</i> – MELOXICAM , meloxicam 15 mg tablet, 30	QA	RW
9435N	<i>Metex XR</i> – METFORMIN , metformin hydrochloride 500 mg tablet: modified release, 120 tablets	QA	RW
8607B	<i>Formet 1000</i> – METFORMIN , metformin hydrochloride 1 g tablet, 90	QA	RW
1646P	<i>Anamorph</i> – MORPHINE , morphine sulfate 30 mg tablet, 20	FM	RW
5163R	<i>Anamorph</i> – MORPHINE , morphine sulfate 30 mg tablet, 20 (Dental)	FM	RW
5573H	<i>Nicotinell Step 3</i> – NICOTINE , nicotine 7 mg/24 hours patch, 28	NC	ON
5572G	<i>Nicotinell Step 2</i> – NICOTINE , nicotine 14 mg/24 hours patch, 28	NC	ON
3414Q	<i>Nicotinell Step 1</i> – NICOTINE , nicotine 21 mg/24 hours patch, 28	NC	ON
5571F	<i>Nicotinell Step 1</i> – NICOTINE , nicotine 21 mg/24 hours patch, 28	NC	ON
1505F	<i>Nizac</i> – NIZATIDINE , nizatidine 150 mg capsule, 60	LN	RF
1505F	<i>Tazac</i> – NIZATIDINE , nizatidine 150 mg capsule, 60	AS	RW
1504E	<i>Nizac</i> – NIZATIDINE , nizatidine 300 mg capsule, 30	LN	RF
1504E	<i>Tazac</i> – NIZATIDINE , nizatidine 300 mg capsule, 30	AS	RW
3010K	<i>Roxin</i> – NORFLOXACIN , norfloxacin 400 mg tablet, 14	QA	RW
2522R	<i>Allegron</i> – NORTRIPTYLINE , nortriptyline 10 mg tablet, 50	AS	RW
2523T	<i>Allegron</i> – NORTRIPTYLINE , nortriptyline 25 mg tablet, 50	AS	RW
3133X	<i>Murelax</i> – OXAZEPAM , oxazepam 30 mg tablet, 25	FM	RW
3135B	<i>Murelax</i> – OXAZEPAM , oxazepam 30 mg tablet, 25	FM	RW
5193H	<i>Murelax</i> – OXAZEPAM , oxazepam 30 mg tablet, 25 (Dental)	FM	RW
8399C	<i>Sozol</i> – PANTOPRAZOLE , pantoprazole 20 mg tablet: enteric, 30 tablets	QA	RW

8007K	Sozol – PANTOPRAZOLE , pantoprazole 40 mg tablet: enteric, 30	QA	RW
8008L	Sozol – PANTOPRAZOLE , pantoprazole 40 mg tablet: enteric, 30	QA	RW
2242B	Extine 20 – PAROXETINE , paroxetine 20 mg tablet, 30	QA	RW
3050M	Indosyl Mono 2 – PERINDOPRIL , perindopril erbumine 2 mg tablet, 30	FM	RW
3051N	Indosyl Mono 4 – PERINDOPRIL , perindopril erbumine 4 mg tablet, 30	FM	RW
8704D	Indosyl Mono 8 – PERINDOPRIL , perindopril erbumine 8 mg tablet, 30	FM	RW
8449Q	Indosyl Combi 4/1.25 – PERINDOPRIL + INDAPAMIDE , perindopril erbumine 4 mg + indapamide hemihydrate 1.25 mg tablet, 30	QA	RW
8694N	Acpio 15 – PIOGLITAZONE , pioglitazone 15 mg tablet, 28	QA	RF
8695P	Acpio 30 – PIOGLITAZONE , pioglitazone 30 mg tablet, 28	QA	RF
8696Q	Acpio 45 – PIOGLITAZONE , pioglitazone 45 mg tablet, 28	QA	RF
9151P	Simipex 0.125 – PRAMIPEXOLE , pramipexole hydrochloride monohydrate 125 microgram tablet, 30	QA	RW
9152Q	Simipex 0.25 – PRAMIPEXOLE , pramipexole hydrochloride monohydrate 250 microgram tablet, 100	QA	RW
9153R	Simipex 1 – PRAMIPEXOLE , pramipexole hydrochloride monohydrate 1 mg tablet, 100	QA	RW
2833D	Lipostat 10 – PRAVASTATIN , pravastatin sodium 10 mg tablet, 30	QA	RF
2833D	Pravachol – PRAVASTATIN , pravastatin sodium 10 mg tablet, 30	FM	RW
9237E	Lipostat 10 – PRAVASTATIN , pravastatin sodium 10 mg tablet, 30	QA	RF
9237E	Pravachol – PRAVASTATIN , pravastatin sodium 10 mg tablet, 30	FM	RW
2834E	Lipostat 20 – PRAVASTATIN , pravastatin sodium 20 mg tablet, 30	QA	RF
2834E	Pravachol – PRAVASTATIN , pravastatin sodium 20 mg tablet, 30	FM	RW
9238F	Lipostat 20 – PRAVASTATIN , pravastatin sodium 20 mg tablet, 30	QA	RF
9238F	Pravachol – PRAVASTATIN , pravastatin sodium 20 mg tablet, 30	FM	RW
8197K	Lipostat 40 – PRAVASTATIN , pravastatin sodium 40 mg tablet, 30	QA	RF
8197K	Pravachol – PRAVASTATIN , pravastatin sodium 40 mg tablet, 30	FM	RW
9239G	Lipostat 40 – PRAVASTATIN , pravastatin sodium 40 mg tablet, 30	QA	RF
9239G	Pravachol – PRAVASTATIN , pravastatin sodium 40 mg tablet, 30	FM	RW
8829Q	Lipostat 80 – PRAVASTATIN , pravastatin sodium 80 mg tablet, 30	QA	RF
8829Q	Pravachol – PRAVASTATIN , pravastatin sodium 80 mg tablet, 30	FM	RW
9240H	Lipostat 80 – PRAVASTATIN , pravastatin sodium 80 mg tablet, 30	QA	RF
9240H	Pravachol – PRAVASTATIN , pravastatin sodium 80 mg tablet, 30	FM	RW
2893G	ProCalm – PROCHLORPERAZINE , prochlorperazine maleate 5 mg tablet, 25	QA	RW
5205Y	ProCalm – PROCHLORPERAZINE , prochlorperazine maleate 5 mg tablet, 25 (Dental)	QA	RW
1953T	Pro-Banthine – PROPANTHELINE , propantheline bromide 15 mg tablet, 100	QA	RW
1966L	Daraprim – PYRIMETHAMINE , pyrimethamine 25 mg tablet, 50	AS	RW
1968N	Acquin Aspen 5 – QUINAPRIL , quinapril 5 mg tablet, 30	AS	RW
1969P	Acquin Aspen 10 – QUINAPRIL , quinapril 10 mg tablet, 30	AS	RW
1970Q	Acquin Aspen 20 – QUINAPRIL , quinapril 20 mg tablet, 30	AS	RW
1975Y	Quinate – QUININE , quinine sulfate 300 mg tablet, 50	AS	RW
1978D	Ausran – RANITIDINE , ranitidine 150 mg tablet, 60	QA	RW
1977C	Ausran – RANITIDINE , ranitidine 300 mg tablet, 30	QA	RW
8621R	Risedro once a week – RISEDRONATE , risedronate sodium 35 mg tablet, 4	QA	RW
8787L	Rispa – RISPERIDONE , risperidone 500 microgram tablet, 60	QA	RW
8869T	Rispa – RISPERIDONE , risperidone 500 microgram tablet, 60	QA	RW

3169T	<i>Rispa</i> – RISPERIDONE , risperidone 1 mg tablet, 60	QA	RW
8789N	<i>Rispa</i> – RISPERIDONE , risperidone 1 mg tablet, 60	QA	RW
3170W	<i>Rispa</i> – RISPERIDONE , risperidone 2 mg tablet, 60	QA	RW
9079W	<i>Rispa</i> – RISPERIDONE , risperidone 2 mg tablet, 60	QA	RW
3171X	<i>Rispa</i> – RISPERIDONE , risperidone 3 mg tablet, 60	QA	RW
3172Y	<i>Rispa</i> – RISPERIDONE , risperidone 4 mg tablet, 60	QA	RW
1760P	<i>Roxar 150</i> – ROXITHROMYCIN , roxithromycin 150 mg tablet, 10	QA	RW
5260W	<i>Roxar 150</i> – ROXITHROMYCIN , roxithromycin 150 mg tablet, 10 (Dental)	QA	RW
5261X	<i>Roxar 300</i> – ROXITHROMYCIN , roxithromycin 300 mg tablet, 5 (Dental)	QA	RW
8016X	<i>Roxar 300</i> – ROXITHROMYCIN , roxithromycin 300 mg tablet, 5	QA	RW
2236Q	<i>Sertra 50</i> – SERTRALINE , sertraline 50 mg tablet, 30	QA	RW
2237R	<i>Sertra 100</i> – SERTRALINE , sertraline 100 mg tablet, 30	QA	RW
2011W	<i>Simvar 10</i> – SIMVASTATIN , simvastatin 10 mg tablet, 30	QA	RW
9242K	<i>Simvar 10</i> – SIMVASTATIN , simvastatin 10 mg tablet, 30	QA	RW
2012X	<i>Simvar 20</i> – SIMVASTATIN , simvastatin 20 mg tablet, 30	QA	RW
9243L	<i>Simvar 20</i> – SIMVASTATIN , simvastatin 20 mg tablet, 30	QA	RW
8173E	<i>Simvar 40</i> – SIMVASTATIN , simvastatin 40 mg tablet, 30	QA	RW
9244M	<i>Simvar 40</i> – SIMVASTATIN , simvastatin 40 mg tablet, 30	QA	RW
8313M	<i>Simvar 80</i> – SIMVASTATIN , simvastatin 80 mg tablet, 30	QA	RW
9245N	<i>Simvar 80</i> – SIMVASTATIN , simvastatin 80 mg tablet, 30	QA	RW
8398B	<i>Solavert</i> – SOTALOL , sotalol hydrochloride 80 mg tablet, 60	QA	RF
8398B	<i>Sotacor</i> – SOTALOL , sotalol hydrochloride 80 mg tablet, 60	FM	RW
2043M	<i>Solavert</i> – SOTALOL , sotalol hydrochloride 160 mg tablet, 60	QA	RF
2043M	<i>Sotacor</i> – SOTALOL , sotalol hydrochloride 160 mg tablet, 60	FM	RW
8144P	<i>Sumagran Aspen 50</i> – SUMATRIPTAN , SUMATRIPTAN Tablet 50 mg (as succinate), 2	AS	RW
8355R	<i>Teltartan</i> – TELMISARTAN , telmisartan 40 mg tablet, 28	QA	RW
8356T	<i>Teltartan</i> – TELMISARTAN , telmisartan 80 mg tablet, 28	QA	RW
8622T	<i>Teltartan HCT 40/12.5</i> – TELMISARTAN + HYDROCHLOROTHIAZIDE , telmisartan 40 mg + hydrochlorothiazide 12.5 mg tablet, 28	QA	RW
8623W	<i>Teltartan HCT 80/12.5</i> – TELMISARTAN + HYDROCHLOROTHIAZIDE , telmisartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28	QA	RW
9381R	<i>Teltartan HCT 80/25</i> – TELMISARTAN + HYDROCHLOROTHIAZIDE , telmisartan 80 mg + hydrochlorothiazide 25 mg tablet, 28	QA	RW
2285G	<i>Tamsil</i> – TERBINAFINE , terbinafine 250 mg tablet, 42	QA	RW
2804N	<i>Tamsil</i> – TERBINAFINE , terbinafine 250 mg tablet, 42	QA	RW
8163P	<i>Epiramax 25</i> – TOPIRAMATE , topiramate 25 mg tablet, 60	QA	RW
8164Q	<i>Epiramax 50</i> – TOPIRAMATE , topiramate 50 mg tablet, 60	QA	RW
8165R	<i>Epiramax 100</i> – TOPIRAMATE , topiramate 100 mg tablet, 60	QA	RW
8166T	<i>Epiramax 200</i> – TOPIRAMATE , topiramate 200 mg tablet, 60	QA	RW
2791X	<i>Dolapril 0.5</i> – TRANDOLAPRIL , trandolapril 500 microgram capsule, 28	QA	RW
2792Y	<i>Dolapril 1</i> – TRANDOLAPRIL , trandolapril 1 mg capsule, 28	QA	RW
2793B	<i>Dolapril 2</i> – TRANDOLAPRIL , trandolapril 2 mg capsule, 28	QA	RW
8758Y	<i>Dolapril 4</i> – TRANDOLAPRIL , trandolapril 4 mg capsule, 28	QA	RW
2666H	<i>Triprim</i> – TRIMETHOPRIM , trimethoprim 300 mg tablet, 7	QA	RW
2922T	<i>Triprim</i> – TRIMETHOPRIM , trimethoprim 300 mg tablet, 7	QA	RW

3103H	<i>Seprin</i> – TRIMETHOPRIM + SULFAMETHOXAZOLE , trimethoprim 40 mg/5 mL + sulfamethoxazole 200 mg/5 mL oral liquid, 100 mL	QA	RW
3391L	<i>Seprin</i> – TRIMETHOPRIM + SULFAMETHOXAZOLE , trimethoprim 40 mg/5 mL + sulfamethoxazole 200 mg/5 mL oral liquid, 100 mL (Dental)	QA	RW
2951H	<i>Seprin Forte</i> – TRIMETHOPRIM + SULFAMETHOXAZOLE , trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10	QA	RW
3390K	<i>Seprin Forte</i> – TRIMETHOPRIM + SULFAMETHOXAZOLE , trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10 (Dental)	QA	RW
5480K	<i>Valnir</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 30	QA	OW
5480K	<i>Valtrex</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 30	AS	RW
5480K	<i>Zelitrex</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 30	FM	RF
8064K	<i>Valnir</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 42	QA	OW
8064K	<i>Valtrex</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 42	AS	RW
8064K	<i>Zelitrex</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 42	FM	RF
8133C	<i>Valnir</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 10	QA	OW
8133C	<i>Valtrex</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 10	AS	RW
8133C	<i>Zelitrex</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 10	FM	RF
8134D	<i>Valnir</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 30	QA	OW
8134D	<i>Valtrex</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 30	AS	RW
8134D	<i>Zelitrex</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 30	FM	RF
2289L	<i>Valproase 200</i> – VALPROATE , valproate sodium 200 mg tablet: enteric, 100	QA	RW
2290M	<i>Valproase 500</i> – VALPROATE , valproate sodium 500 mg tablet: enteric, 100	QA	RW
2206D	<i>Veracaps SR</i> – VERAPAMIL , verapamil hydrochloride 160 mg capsule: modified release, 30 capsules	QA	RW
2207E	<i>Veracaps SR</i> – VERAPAMIL , verapamil hydrochloride 240 mg capsule: modified release, 30 capsules	QA	RW

Advance Notices

1 March 2016

Deletion – Brand

2751T	<i>Amlodipine-DRLA, RZ</i> – AMLODIPINE , amlodipine 5 mg tablet, 30
2752W	<i>Amlodipine-DRLA, RZ</i> – AMLODIPINE , amlodipine 10 mg tablet, 30
8179L	<i>Anastrozole-DRLA, RZ</i> – ANASTROZOLE , anastrozole 1 mg tablet, 30
8179L	<i>Pharmacy Choice Anastrozole, RI</i> – ANASTROZOLE , anastrozole 1 mg tablet, 30
1208N	<i>Ciprofloxacin-DRLA, RZ</i> – CIPROFLOXACIN , ciprofloxacin 250 mg tablet, 14
1209P	<i>Ciprofloxacin-DRLA, RZ</i> – CIPROFLOXACIN , ciprofloxacin 500 mg tablet, 14
1210Q	<i>Ciprofloxacin-DRLA, RZ</i> – CIPROFLOXACIN , ciprofloxacin 750 mg tablet, 14
9155W	<i>Duloxetine-DRLA, RZ</i> – DULOXETINE , duloxetine 30 mg capsule: enteric, 28
9156X	<i>Duloxetine-DRLA, RZ</i> – DULOXETINE , duloxetine 60 mg capsule: enteric, 28
8246B	<i>Irbesartan-DRLA, RZ</i> – IRBESARTAN , irbesartan 75 mg tablet, 30
8247C	<i>Irbesartan-DRLA, RZ</i> – IRBESARTAN , irbesartan 150 mg tablet, 30
8248D	<i>Irbesartan-DRLA, RZ</i> – IRBESARTAN , irbesartan 300 mg tablet, 30
8245Y	<i>Letrozole-DRLA, RZ</i> – LETROZOLE , letrozole 2.5 mg tablet, 30
8245Y	<i>Pharmacy Choice Letrozole, RI</i> – LETROZOLE , letrozole 2.5 mg tablet, 30
2456G	<i>Lisinopril-DRLA, RZ</i> – LISINOPRIL , lisinopril 5 mg tablet, 30
2457H	<i>Lisinopril-DRLA, RZ</i> – LISINOPRIL , lisinopril 10 mg tablet, 30

2458J	<i>Lisinopril-DRLA, RZ</i> – LISINOPRIL , lisinopril 20 mg tablet, 30
3381Y	<i>Pharmacy Choice Olanzapine ODT, RI</i> – OLANZAPINE , OLANZAPINE Tablet 5 mg (orally disintegrating), 28
3382B	<i>Pharmacy Choice Olanzapine ODT, RI</i> – OLANZAPINE , OLANZAPINE Tablet 10 mg (orally disintegrating), 28
8170B	<i>Pharmacy Choice Olanzapine, RI</i> – OLANZAPINE , olanzapine 2.5 mg tablet, 28
8185T	<i>Pharmacy Choice Olanzapine, RI</i> – OLANZAPINE , olanzapine 5 mg tablet, 28
8186W	<i>Pharmacy Choice Olanzapine, RI</i> – OLANZAPINE , olanzapine 7.5 mg tablet, 28
8187X	<i>Pharmacy Choice Olanzapine, RI</i> – OLANZAPINE , olanzapine 10 mg tablet, 28
8456C	<i>Pharmacy Choice Quetiapine, RI</i> – QUETIAPINE , quetiapine 25 mg tablet, 60
8457D	<i>Pharmacy Choice Quetiapine, RI</i> – QUETIAPINE , quetiapine 100 mg tablet, 90
8458E	<i>Pharmacy Choice Quetiapine, RI</i> – QUETIAPINE , quetiapine 200 mg tablet, 60
8580N	<i>Pharmacy Choice Quetiapine, RI</i> – QUETIAPINE , quetiapine 300 mg tablet, 60
3169T	<i>Risperidone-DRLA, RZ</i> – RISPERIDONE , risperidone 1 mg tablet, 60
3170W	<i>Risperidone-DRLA, RZ</i> – RISPERIDONE , risperidone 2 mg tablet, 60
3171X	<i>Risperidone-DRLA, RZ</i> – RISPERIDONE , risperidone 3 mg tablet, 60
3172Y	<i>Risperidone-DRLA, RZ</i> – RISPERIDONE , risperidone 4 mg tablet, 60
8787L	<i>Risperidone-DRLA, RZ</i> – RISPERIDONE , risperidone 500 microgram tablet, 60
8789N	<i>Risperidone-DRLA, RZ</i> – RISPERIDONE , risperidone 1 mg tablet, 60
8869T	<i>Risperidone-DRLA, RZ</i> – RISPERIDONE , risperidone 500 microgram tablet, 60
9079W	<i>Risperidone-DRLA, RZ</i> – RISPERIDONE , risperidone 2 mg tablet, 60
2236Q	<i>Sertraline-DRLA, RZ</i> – SERTRALINE , sertraline 50 mg tablet, 30
2237R	<i>Sertraline-DRLA, RZ</i> – SERTRALINE , sertraline 100 mg tablet, 30
2011W	<i>Simvastatin-DRLA, RZ</i> – SIMVASTATIN , simvastatin 10 mg tablet, 30
2012X	<i>Simvastatin-DRLA, RZ</i> – SIMVASTATIN , simvastatin 20 mg tablet, 30
8173E	<i>Simvastatin-DRLA, RZ</i> – SIMVASTATIN , simvastatin 40 mg tablet, 30
8313M	<i>Simvastatin-DRLA, RZ</i> – SIMVASTATIN , simvastatin 80 mg tablet, 30
9242K	<i>Simvastatin-DRLA, RZ</i> – SIMVASTATIN , simvastatin 10 mg tablet, 30
9243L	<i>Simvastatin-DRLA, RZ</i> – SIMVASTATIN , simvastatin 20 mg tablet, 30
9244M	<i>Simvastatin-DRLA, RZ</i> – SIMVASTATIN , simvastatin 40 mg tablet, 30
9245N	<i>Simvastatin-DRLA, RZ</i> – SIMVASTATIN , simvastatin 80 mg tablet, 30
2285G	<i>Pharmacy Choice Terbinafine, RI</i> – TERBINAFINE , terbinafine 250 mg tablet, 42
2804N	<i>Pharmacy Choice Terbinafine, RI</i> – TERBINAFINE , terbinafine 250 mg tablet, 42

1 April 2016

Deletion – Brand

3065H	<i>Visken 15, NV</i> – PINDOLOL , pindolol 15 mg tablet, 50
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1 May 2016

Deletion – Brand

2022K	<i>Ridaura, GH</i> – AURANOFIN , AURANOFIN Capsule 3 mg, 60
1967M	<i>Micronor, JC</i> – NORETHISTERONE , norethisterone 350 microgram tablet, 112 [4 x 28]
8668F	<i>Tritace Titration Pack, SW</i> – RAMIPRIL , ramipril 2.5 mg tablet [7 tablets] (&) ramipril 5 mg tablet [21 tablets] (&) ramipril 10 mg capsule [10 capsules], 1 pack
8788M	<i>Risperdal Quicklet, JC</i> – RISPERIDONE , risperidone 500 microgram tablet: orally disintegrating, 28
8790P	<i>Risperdal Quicklet, JC</i> – RISPERIDONE , risperidone 1 mg tablet: orally disintegrating, 28

8792R	<i>Risperdal Quicklet, JC</i> – RISPERIDONE , risperidone 1 mg tablet: orally disintegrating, 28
8794W	<i>Risperdal Quicklet, JC</i> – RISPERIDONE , risperidone 2 mg tablet: orally disintegrating, 28
8870W	<i>Risperdal Quicklet, JC</i> – RISPERIDONE , risperidone 500 microgram tablet: orally disintegrating, 28
9075P	<i>Risperdal Quicklet, JC</i> – RISPERIDONE , risperidone 3 mg tablet: orally disintegrating, 28
9076Q	<i>Risperdal Quicklet, JC</i> – RISPERIDONE , risperidone 4 mg tablet: orally disintegrating, 28
9080X	<i>Risperdal Quicklet, JC</i> – RISPERIDONE , risperidone 2 mg tablet: orally disintegrating, 28

Palliative Care

Additions

Addition – Item

10601Y	FENTANYL , fentanyl 100 microgram tablet: sublingual, 10 (<i>Abstral</i>)
10602B	FENTANYL , fentanyl 100 microgram tablet: sublingual, 30 (<i>Abstral</i>)
10600X	FENTANYL , fentanyl 200 microgram tablet: sublingual, 10 (<i>Abstral</i>)
10607G	FENTANYL , fentanyl 200 microgram tablet: sublingual, 30 (<i>Abstral</i>)
10606F	FENTANYL , fentanyl 300 microgram tablet: sublingual, 10 (<i>Abstral</i>)
10610K	FENTANYL , fentanyl 300 microgram tablet: sublingual, 30 (<i>Abstral</i>)
10603C	FENTANYL , fentanyl 400 microgram tablet: sublingual, 10 (<i>Abstral</i>)
10608H	FENTANYL , fentanyl 400 microgram tablet: sublingual, 30 (<i>Abstral</i>)
10604D	FENTANYL , fentanyl 600 microgram tablet: sublingual, 10 (<i>Abstral</i>)
10613N	FENTANYL , fentanyl 600 microgram tablet: sublingual, 30 (<i>Abstral</i>)
10611L	FENTANYL , fentanyl 800 microgram tablet: sublingual, 30 (<i>Abstral</i>)
10612M	FENTANYL , fentanyl 800 microgram tablet: sublingual, 10 (<i>Abstral</i>)

Alterations

Changes to Restrictions

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

5401G	FENTANYL , FENTANYL Lozenge 200 micrograms (as citrate), 9 (<i>Actiq</i>)
5402H	FENTANYL , FENTANYL Lozenge 400 micrograms (as citrate), 9 (<i>Actiq</i>)
5403J	FENTANYL , FENTANYL Lozenge 600 micrograms (as citrate), 9 (<i>Actiq</i>)
5404K	FENTANYL , FENTANYL Lozenge 800 micrograms (as citrate), 9 (<i>Actiq</i>)
5405L	FENTANYL , FENTANYL Lozenge 1200 micrograms (as citrate), 9 (<i>Actiq</i>)
5406M	FENTANYL , FENTANYL Lozenge 1600 micrograms (as citrate), 9 (<i>Actiq</i>)
5407N	FENTANYL , FENTANYL Lozenge 200 micrograms (as citrate), 30 (<i>Actiq</i>)
5408P	FENTANYL , FENTANYL Lozenge 400 micrograms (as citrate), 30 (<i>Actiq</i>)
5409Q	FENTANYL , FENTANYL Lozenge 600 micrograms (as citrate), 30 (<i>Actiq</i>)
5410R	FENTANYL , FENTANYL Lozenge 800 micrograms (as citrate), 30 (<i>Actiq</i>)
5411T	FENTANYL , FENTANYL Lozenge 1200 micrograms (as citrate), 30 (<i>Actiq</i>)
5412W	FENTANYL , FENTANYL Lozenge 1600 micrograms (as citrate), 30 (<i>Actiq</i>)

Alteration – Manufacturer Code

		<i>From</i>	<i>To</i>
5355W	<i>Valpam 2</i> – DIAZEPAM , diazepam 2 mg tablet, 50	QA	RW
5357Y	<i>Valpam 2</i> – DIAZEPAM , diazepam 2 mg tablet, 50	QA	RW
5356X	<i>Valpam 5</i> – DIAZEPAM , diazepam 5 mg tablet, 50	QA	RW
5358B	<i>Valpam 5</i> – DIAZEPAM , diazepam 5 mg tablet, 50	QA	RW
5372R	<i>Murelax</i> – OXAZEPAM , oxazepam 30 mg tablet, 25	FM	RW
5374W	<i>Murelax</i> – OXAZEPAM , oxazepam 30 mg tablet, 25	FM	RW

Highly Specialised Drugs Program (Private Hospital)

Additions

Addition – Brand

9607P	<i>Movapo, TD</i> – APOMORPHINE , apomorphine hydrochloride 20 mg/2 mL injection, 5 x 2 mL ampoules
9640J	<i>Movapo, TD</i> – APOMORPHINE , apomorphine hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules
6328C	<i>TACROLIMUS APOTEX, TX</i> – TACROLIMUS , tacrolimus 500 microgram capsule, 100
6216E	<i>TACROLIMUS APOTEX, TX</i> – TACROLIMUS , tacrolimus 1 mg capsule, 100
6217F	<i>TACROLIMUS APOTEX, TX</i> – TACROLIMUS , tacrolimus 5 mg capsule, 50

Deletions

Deletion – Item

6426F	OCTREOTIDE , octreotide 10 mg injection: modified release [1 x 10 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack (<i>Sandostatin LAR</i>)
6427G	OCTREOTIDE , octreotide 20 mg injection: modified release [1 x 20 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack (<i>Sandostatin LAR</i>)
6428H	OCTREOTIDE , octreotide 30 mg injection: modified release [1 x 30 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack (<i>Sandostatin LAR</i>)

Deletion – Brand

9607P	<i>Apomine, HH</i> – APOMORPHINE , apomorphine hydrochloride 20 mg/2 mL injection, 5 x 2 mL ampoules
9640J	<i>Apomine, HH</i> – APOMORPHINE , apomorphine hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules

Deletion – Equivalence Indicator

10566D	<i>Sandostatin LAR, NV</i> – OCTREOTIDE , octreotide 10 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack
10549F	<i>Sandostatin LAR, NV</i> – OCTREOTIDE , octreotide 20 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack
10558Q	<i>Sandostatin LAR, NV</i> – OCTREOTIDE , octreotide 30 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

Alterations

Changes to Restrictions

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

10182X	ECULIZUMAB , eculizumab 300 mg/30 mL injection, 1 x 30 mL vial (<i>Soliris</i>)
10192K	ECULIZUMAB , eculizumab 300 mg/30 mL injection, 1 x 30 mL vial (<i>Soliris</i>)
10194M	ECULIZUMAB , eculizumab 300 mg/30 mL injection, 1 x 30 mL vial (<i>Soliris</i>)
10521R	ECULIZUMAB , eculizumab 300 mg/30 mL injection, 1 x 30 mL vial (<i>Soliris</i>)
10549F	OCTREOTIDE , octreotide 20 mg injection: modified release [1 vial] (& inert substance diluent [2 mL syringe], 1 pack (<i>Sandostatin LAR</i>))
10558Q	OCTREOTIDE , octreotide 30 mg injection: modified release [1 vial] (& inert substance diluent [2 mL syringe], 1 pack (<i>Sandostatin LAR</i>))
10566D	OCTREOTIDE , octreotide 10 mg injection: modified release [1 vial] (& inert substance diluent [2 mL syringe], 1 pack (<i>Sandostatin LAR</i>))
6469L	THALIDOMIDE , thalidomide 50 mg capsule, 28 (<i>Thalomid</i>)
9684Q	THALIDOMIDE , thalidomide 100 mg capsule, 28 (<i>Thalomid</i>)

Alteration – Manufacturer Code

		<i>From</i>	<i>To</i>
6280M	<i>Valtrex</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 100	AS	RW
6280M	<i>Zelitrex</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 100	FM	RF

Highly Specialised Drugs Program (Public Hospital)

Additions

Addition – Brand

5609F	<i>Movapo, TD</i> – APOMORPHINE , apomorphine hydrochloride 20 mg/2 mL injection, 5 x 2 mL ampoules
5610G	<i>Movapo, TD</i> – APOMORPHINE , apomorphine hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules
9558C	<i>TACROLIMUS APOTEX, TX</i> – TACROLIMUS , tacrolimus 500 microgram capsule, 100
9560E	<i>TACROLIMUS APOTEX, TX</i> – TACROLIMUS , tacrolimus 1 mg capsule, 100
9561F	<i>TACROLIMUS APOTEX, TX</i> – TACROLIMUS , tacrolimus 5 mg capsule, 50

Deletions

Deletion – Item

9511N	OCTREOTIDE , octreotide 10 mg injection: modified release [1 x 10 mg vial] (& inert substance diluent [1 x 2.5 mL syringe], 1 pack (<i>Sandostatin LAR</i>))
9512P	OCTREOTIDE , octreotide 20 mg injection: modified release [1 x 20 mg vial] (& inert substance diluent [1 x 2.5 mL syringe], 1 pack (<i>Sandostatin LAR</i>))
9513Q	OCTREOTIDE , octreotide 30 mg injection: modified release [1 x 30 mg vial] (& inert substance diluent [1 x 2.5 mL syringe], 1 pack (<i>Sandostatin LAR</i>))

Deletion – Brand

5609F	<i>Apomine, HH</i> – APOMORPHINE , apomorphine hydrochloride 20 mg/2 mL injection, 5 x 2 mL ampoules
5610G	<i>Apomine, HH</i> – APOMORPHINE , apomorphine hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules

Deletion – Equivalence Indicator

10543X	<i>Sandostatin LAR, NV</i> – OCTREOTIDE , octreotide 10 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack
10533J	<i>Sandostatin LAR, NV</i> – OCTREOTIDE , octreotide 20 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack
10550G	<i>Sandostatin LAR, NV</i> – OCTREOTIDE , octreotide 30 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

Alterations

Changes to Restrictions

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

10183Y	ECULIZUMAB , eculizumab 300 mg/30 mL injection, 1 x 30 mL vial (<i>Soliris</i>)
10190H	ECULIZUMAB , eculizumab 300 mg/30 mL injection, 1 x 30 mL vial (<i>Soliris</i>)
10191J	ECULIZUMAB , eculizumab 300 mg/30 mL injection, 1 x 30 mL vial (<i>Soliris</i>)
10525Y	ECULIZUMAB , eculizumab 300 mg/30 mL injection, 1 x 30 mL vial (<i>Soliris</i>)
10533J	OCTREOTIDE , octreotide 20 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack (<i>Sandostatin LAR</i>)
10543X	OCTREOTIDE , octreotide 10 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack (<i>Sandostatin LAR</i>)
10550G	OCTREOTIDE , octreotide 30 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack (<i>Sandostatin LAR</i>)
9566L	THALIDOMIDE , thalidomide 50 mg capsule, 28 (<i>Thalomid</i>)
9667T	THALIDOMIDE , thalidomide 100 mg capsule, 28 (<i>Thalomid</i>)

Alteration – Manufacturer Code

		<i>From</i>	<i>To</i>
9568N	<i>Valtrex</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 100	AS	RW
9568N	<i>Zelitrex</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 100	FM	RF

Highly Specialised Drugs Program (Community Access)

Deletions

Deletion – Item

10325K	STAVUDINE , stavudine 20 mg capsule, 60 (<i>Zerit</i>)
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Alterations

Alteration – Manufacturer Code

		<i>From</i>	<i>To</i>
10338D	<i>Zeffix</i> – LAMIVUDINE , lamivudine 5 mg/mL oral liquid, 240 mL	AS	RW
10315X	<i>Zeffix</i> – LAMIVUDINE , lamivudine 100 mg tablet, 28	AS	RW

Botulinum Toxin Program

Alterations

Alteration – Maximum Quantity

		From	To
10253P	INCOBOTULINUMTOXINA , incobotulinumtoxinA 100 mouse LD50 units injection, 1 x 100 mouse LD50 units vial (<i>Xeomin</i>)	3	4

Repatriation Pharmaceutical Benefits

Alterations

Changes to Restrictions

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

4717G	BANDAGE CALICO , bandage calico large bandage: triangular, 1 bandage (<i>Handy 36361414</i>)
4654Y	BANDAGE COMPRESSION , BANDAGE-COMPRESSION Bandage, short stretch, 8 cm x 2.6 m, 1 (<i>Comprilan 01027-00</i>)
4748X	BANDAGE COMPRESSION , bandage compression 10 cm x 3 m bandage: high stretch, 1 bandage (<i>Surepress 650947, Tensopress 71723-00</i>)
4662J	BANDAGE RETENTION COHESIVE LIGHT , bandage retention cohesive light 10 cm x 2 m bandage, 1 (<i>Handygauze Cohesive 8635</i>)
4718H	BANDAGE RETENTION COHESIVE LIGHT , bandage retention cohesive light 2.5 cm x 2 m bandage, 2 (<i>Handygauze Cohesive 8631</i>)
4719J	BANDAGE RETENTION COHESIVE LIGHT , bandage retention cohesive light 6 cm x 2 m bandage, 1 (<i>Handygauze Cohesive 8633</i>)
4727T	BANDAGE RETENTION COTTON CREPE , bandage retention cotton crepe 5 cm x 2.3 m bandage, 1 (<i>Telfa 8252F, Tensocrepe 36300501</i>)
4728W	BANDAGE RETENTION COTTON CREPE , bandage retention cotton crepe 7.5 cm x 2.3 m bandage, 1 (<i>Telfa 8253F, Tensocrepe 36307501</i>)
4729X	BANDAGE RETENTION COTTON CREPE , bandage retention cotton crepe 10 cm x 2.3 m bandage, 1 (<i>Telfa 8254F, Tensocrepe 36301001</i>)
4150K	BROMAZEPAM , bromazepam 3 mg tablet, 30 (<i>Lexotan</i>)
4151L	BROMAZEPAM , bromazepam 6 mg tablet, 30 (<i>Lexotan</i>)
4707R	DRESSING GAUZE ABSORBENT , dressing gauze absorbent 5 cm x 5 cm pad, 100 (<i>Handy 71117-05</i>)
4708T	DRESSING GAUZE ABSORBENT , dressing gauze absorbent 10 cm x 10 cm pad, 100 (<i>Handy 71117-06</i>)
4216X	FLUNITRAZEPAM , flunitrazepam 1 mg tablet, 30 (<i>Hypnodorm</i>)
4767X	GAUZE AND COTTON TISSUE COMBINE ROLL , gauze and cotton tissue combine roll 9 cm x 10 m roll: wrapped pack, 1 pack (<i>BSN 2902165</i>)
4780N	TAPE PLASTER ADHESIVE ELASTIC , tape plaster adhesive elastic 2.5 cm x 2.5 m tape, 1 roll (<i>Leukoplast 01071-00</i>)
4781P	TAPE PLASTER ADHESIVE ELASTIC , tape plaster adhesive elastic 5 cm x 2.5 m tape, 1 roll (<i>Leukoplast 01072-00</i>)
4782Q	TAPE PLASTER ADHESIVE ELASTIC , tape plaster adhesive elastic 7.5 cm x 2.5 m tape, 1 roll (<i>Leukoplast 01073-00</i>)
4783R	TAPE PLASTER ADHESIVE HYPOALLERGENIC , tape plaster adhesive hypoallergenic 1.25 cm x 5 m tape, 1 roll (<i>Leukopor 2471</i>)
4785W	TAPE PLASTER ADHESIVE HYPOALLERGENIC , tape plaster adhesive hypoallergenic 1.25 cm x 5 m tape, 1 roll (<i>Leukosilk 1021</i>)
4787Y	TAPE PLASTER ADHESIVE HYPOALLERGENIC , tape plaster adhesive hypoallergenic 2.5 cm x 5 m tape, 1 roll (<i>Leukosilk 1022</i>)

4788B	TAPE PLASTER ADHESIVE HYPOALLERGENIC , tape plaster adhesive hypoallergenic 5 cm x 5 m stretch tape, 1 roll (<i>Leukoflex 1124</i>)
4789C	TAPE PLASTER ADHESIVE HYPOALLERGENIC , tape plaster adhesive hypoallergenic 5 cm x 5 m stretch tape, 1 roll (<i>Leukosilk 1024</i>)
4790D	TAPE PLASTER ADHESIVE HYPOALLERGENIC , tape plaster adhesive hypoallergenic 5 cm x 5 m stretch tape, 1 roll (<i>Leukopor 2474</i>)
4794H	TAPE PLASTER ADHESIVE HYPOALLERGENIC , tape plaster adhesive hypoallergenic 2.5 cm x 5 m tape, 1 roll (<i>Leukopor 2472</i>)

Alteration – Manufacturer Code

		<i>From</i>	<i>To</i>
4591P	<i>Gabapentin Aspen 100</i> – GABAPENTIN , gabapentin 100 mg capsule, 100	FM	RW
4592Q	<i>Gabapentin Aspen 300</i> – GABAPENTIN , gabapentin 300 mg capsule, 100	FM	RW
4593R	<i>Gabapentin Aspen 400</i> – GABAPENTIN , gabapentin 400 mg capsule, 100	FM	RW
4594T	<i>Gabapentin Aspen 600</i> – GABAPENTIN , gabapentin 600 mg tablet, 100	FM	RW
4595W	<i>Gabapentin Aspen 800</i> – GABAPENTIN , gabapentin 800 mg tablet, 100	FM	RW
4444X	<i>Risedro once a week</i> – RISEDRONATE , risedronate sodium 35 mg tablet, 4	QA	RW
4011D	<i>Tamsil</i> – TERBINAFINE , terbinafine 250 mg tablet, 42	QA	RW

General Pharmaceutical Benefits

FLUCLOXACILLIN

Caution Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

Note Pharmaceutical benefits that have the form flucloxacillin 1 g injection in a pack size of 5 can be substituted for a pack size of 10 in the case of a shortage.

flucloxacillin 1 g injection, 10 x 1 g vials

10605E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	0.5	1	..	*26.96	28.13	^a Hospira Pty Limited [HH]

flucloxacillin 1 g injection, 10 x 1 g vials

10609J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	0.5	*26.96	28.13	^a Hospira Pty Limited [HH]

RISPERIDONE

Note Shared Care Model:

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

Authority required (STREAMLINED)

4246

Schizophrenia

risperidone 500 microgram tablet: orally disintegrating, 28

8870W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*16.11	17.28	Risperdal Quicklet [JC]

RISPERIDONE

Note Shared Care Model:

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

Authority required (STREAMLINED)

4246

Schizophrenia

Authority required (STREAMLINED)

5907

Acute mania

Clinical criteria:

The condition must be associated with bipolar I disorder, **AND**

The treatment must be as adjunctive therapy to mood stabilisers, **AND**

The treatment must be limited to up to 6 months per episode.

risperidone 1 mg tablet, 60

3169T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	20.18	21.35	^a APO-Risperidone [TX] ^a Rispa [RW] ^a Rispericor 1 [CR] ^a Risperidone AN [EA] ^a Risperidone-GA [EF] ^a Risperidone Sandoz [SZ]	^a Ozidal [RA] ^a Risperdal [JC] ^a Risperidone Actavis 1 [ED] ^a Risperidone-DRLA [RZ] ^a Risperidone generichealth [GQ] ^a Rispernia [ER]

^a Rixadone [AF]

risperidone 1 mg tablet: orally disintegrating, 28

8792R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*21.77	22.94	Risperdal Quicklet [JC]

risperidone 1 mg/mL oral liquid, 100 mL

8100H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	111.88	38.30	Risperdal [JC]

risperidone 2 mg tablet, 60

3170W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	32.75	33.92	^a APO-Risperidone [TX] ^a Rispa [RW] ^a Rispericor 2 [CR] ^a Risperidone AN [EA] ^a Risperidone-GA [EF] ^a Risperidone Sandoz [SZ] ^a Rixadone [AF]	^a Ozidal [RA] ^a Risperdal [JC] ^a Risperidone Actavis 2 [ED] ^a Risperidone-DRLA [RZ] ^a Risperidone generichealth [GQ] ^a Rispernia [ER]

risperidone 2 mg tablet: orally disintegrating, 28

8794W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*33.21	34.38	Risperdal Quicklet [JC]

risperidone 3 mg tablet, 60

3171X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	44.85	38.30	^a APO-Risperidone [TX] ^a Rispa [RW] ^a Rispericor 3 [CR] ^a Risperidone AN [EA] ^a Risperidone-GA [EF] ^a Risperidone Sandoz [SZ] ^a Rixadone [AF]	^a Ozidal [RA] ^a Risperdal [JC] ^a Risperidone Actavis 3 [ED] ^a Risperidone-DRLA [RZ] ^a Risperidone generichealth [GQ] ^a Rispernia [ER]

risperidone 3 mg tablet: orally disintegrating, 28

9075P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*44.25	38.30	Risperdal Quicklet [JC]

risperidone 4 mg tablet, 60

3172Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	56.90	38.30	^a APO-Risperidone [TX] ^a Rispa [RW] ^a Rispericor 4 [CR] ^a Risperidone-DRLA [RZ] ^a Risperidone generichealth [GQ] ^a Rispernia [ER]	^a Ozidal [RA] ^a Risperdal [JC] ^a Risperidone AN [EA] ^a Risperidone-GA [EF] ^a Risperidone Sandoz [SZ] ^a Rixadone [AF]

risperidone 4 mg tablet: orally disintegrating, 28

9076Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*55.51	38.30	Risperdal Quicklet [JC]

■ RISPERIDONE

Note Shared Care Model:

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

Authority required (STREAMLINED)

5916

Severe behavioural disturbances

Clinical criteria:

Patient must have autism, **AND**

The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**

The treatment must be in combination with non-pharmacological measures.

Population criteria:

Patient must be under 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or ICD-10 international classification of mental and behavioural disorders.

Authority required (STREAMLINED)

5898

Severe behavioural disturbances

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have autism, **AND**

Patient must have been commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age, **AND**

The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**

The treatment must be in combination with non-pharmacological measures.

Population criteria:

Patient must be aged 18 years or older.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or ICD-10 international classification of mental and behavioural disorders.

risperidone 2 mg tablet, 60

9079W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	32.75	33.92	^a APO-Risperidone [TX] ^a Rispa [RW] ^a Rispericor 2 [CR] ^a Risperidone AN [EA] ^a Risperidone-GA [EF] ^a Risperidone Sandoz [SZ] ^a Rixadone [AF]	^a Ozidal [RA] ^a Risperdal [JC] ^a Risperidone Actavis 2 [ED] ^a Risperidone-DRLA [RZ] ^a Risperidone generichealth [GQ] ^a Rispernia [ER]

risperidone 2 mg tablet: orally disintegrating, 28

9080X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*33.21	34.38	Risperdal Quicklet [JC]

■ RISPERIDONE

Note Shared Care Model:

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

Authority required (STREAMLINED)

4246

Schizophrenia

Authority required (STREAMLINED)

5912

Bipolar I disorder

Clinical criteria:

The condition must be refractory to treatment, **AND**

The treatment must be in combination with lithium or sodium valproate, **AND**

The treatment must be maintenance therapy.

risperidone 25 mg injection: modified release [1 x 25 mg vial] (&) inert substance diluent [1 x 2 mL syringe], 1 pack

8780D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*265.65	38.30	Risperdal Consta [JC]

risperidone 37.5 mg injection: modified release [1 x 37.5 mg vial] (&) inert substance diluent [1 x 2 mL syringe], 1 pack

8781E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*344.65	38.30	Risperdal Consta [JC]

risperidone 50 mg injection: modified release [1 x 50 mg vial] (&) inert substance diluent [1 x 2 mL syringe], 1 pack

8782F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*422.83	38.30	Risperdal Consta [JC]

■ RISPERIDONE

Note Shared Care Model:

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

Note For item codes 8869T and 1846E, pharmaceutical benefits that have the form tablet 0.5 mg are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

5903

Schizophrenia

risperidone 500 microgram tablet, 20

1846E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	3	5	..	*15.48	16.65	^a APO-Risperidone [TX]	^a Risperdal [JC]

risperidone 500 microgram tablet, 60

8869T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.48	16.65	^a Ozidal [RA] ^a Rispericor 0.5 [CR] ^a Risperidone AN [EA] ^a Risperidone-GA [EF] ^a Risperidone Sandoz [SZ] ^a Rixadone [AF]	^a Rispa [RW] ^a Risperidone Actavis 0.5 [ED] ^a Risperidone-DRLA [RZ] ^a Risperidone GH [GQ] ^a Rispernia [ER]

■ RISPERIDONE

Caution In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalities) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.

Note Shared Care Model:

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

Authority required (STREAMLINED)

5897

Behavioural disturbances

Clinical criteria:

The condition must be characterised by psychotic symptoms and aggression, **AND**

Patient must have dementia, **AND**

Patient must have failed to respond to non-pharmacological methods of treatment.

Authority required (STREAMLINED)

5916

Severe behavioural disturbances

Clinical criteria:

Patient must have autism, **AND**

The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**

The treatment must be in combination with non-pharmacological measures.

Population criteria:

Patient must be under 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or ICD-10 international classification of mental and behavioural disorders.

Authority required (STREAMLINED)

5898

Severe behavioural disturbances

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have autism, **AND**

Patient must have been commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age, **AND**

The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**

The treatment must be in combination with non-pharmacological measures.

Population criteria:

Patient must be aged 18 years or older.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or ICD-10 international classification of mental and behavioural disorders.

risperidone 1 mg tablet, 60

8789N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	20.18	21.35	^a APO-Risperidone [TX] ^a Rispa [RW] ^a Rispericor 1 [CR] ^a Risperidone AN [EA] ^a Risperidone-GA [EF] ^a Risperidone Sandoz [SZ] ^a Rixadone [AF]	^a Ozidal [RA] ^a Risperdal [JC] ^a Risperidone Actavis 1 [ED] ^a Risperidone-DRLA [RZ] ^a Risperidone generichealth [GQ] ^a Rispernia [ER]

risperidone 1 mg tablet: orally disintegrating, 28

8790P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*21.77	22.94	Risperdal Quicklet [JC]

risperidone 1 mg/mL oral liquid, 100 mL

9293D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	2	..	111.88	38.30	Risperdal [JC]

risperidone 500 microgram tablet: orally disintegrating, 28

8788M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*16.11	17.28	Risperdal Quicklet [JC]

■ RISPERIDONE

Caution In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalities) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.

Note Shared Care Model:

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

Note For items 8787L and 1842Y, pharmaceutical benefits that have the form tablet 0.5 mg are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

5908

Behavioural disturbances

Clinical criteria:

The condition must be characterised by psychotic symptoms and aggression, **AND**

Patient must have dementia, **AND**

Patient must have failed to respond to non-pharmacological methods of treatment.

Authority required (STREAMLINED)

5911

Severe behavioural disturbances

Clinical criteria:

Patient must have autism, **AND**

The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**

The treatment must be in combination with non-pharmacological measures.

Population criteria:

Patient must be under 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or ICD-10 international classification of mental and behavioural disorders.

Authority required (STREAMLINED)

5902

Severe behavioural disturbances

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have autism, **AND**

Patient must have been commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age, **AND**

The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**

The treatment must be in combination with non-pharmacological measures.

Population criteria:

Patient must be aged 18 years or older.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or ICD-10 international classification of mental and behavioural disorders.

risperidone 500 microgram tablet, 20

1842Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	3	2	..	*15.48	16.65	^a APO-Risperidone [TX]	^a Risperdal [JC]

risperidone 500 microgram tablet, 60

8787L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	15.48	16.65	^a Ozidal [RA] ^a Rispericor 0.5 [CR] ^a Risperidone AN [EA] ^a Risperidone-GA [EF] ^a Risperidone Sandoz [SZ] ^a Rixadone [AF]	^a Rispa [RW] ^a Risperidone Actavis 0.5 [ED] ^a Risperidone-DRLA [RZ] ^a Risperidone GH [GQ] ^a Rispernia [ER]

▪ RUXOLITINIB

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

Note Written applications for authority to prescribe should be forwarded to:

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

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

Note Special Pricing Arrangements apply.

Authority required

High risk and intermediate-2 risk myelofibrosis

Treatment Phase: Initial treatment

Clinical criteria:

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

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

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

Authority required

Intermediate-1 risk myelofibrosis

Treatment Phase: Initial treatment

Clinical criteria:

The condition must be primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis, **AND**

Patient must have severe disease-related symptoms that are resistant, refractory or intolerant to available therapy.

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

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

ruxolitinib 15 mg tablet, 56

10619X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5146.87	38.30	Jakavi [NV]

ruxolitinib 20 mg tablet, 56

10618W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5146.87	38.30	Jakavi [NV]

ruxolitinib 5 mg tablet, 56

10614P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	*5146.87	38.30	Jakavi [NV]

▪ RUXOLITINIB

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

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

Note Special Pricing Arrangements apply.

Authority required

High risk and intermediate-2 risk myelofibrosis

Treatment Phase: Continuing treatment

Clinical criteria:The condition must be primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis, **AND**

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

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

Authority required

Intermediate-1 risk myelofibrosis

Treatment Phase: Continuing treatment

Clinical criteria:The condition must be primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis, **AND**

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

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

Authority required

High risk, intermediate-2 risk and intermediate-1 risk myelofibrosis

Treatment Phase: Grandfathering treatment

Clinical criteria:The condition must be primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis, **AND**

Patient must have previously received non-PBS-subsidised treatment with this drug for this condition before 1 February 2016.

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

(1) A completed authority prescription form; and

(2) A completed Myelofibrosis Authority Application Supporting Information Form, which includes all of the following:

a) A copy of the bone marrow biopsy report confirming diagnosis of myelofibrosis; and

b) A classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS.

(3) Details of previous ruxolitinib treatment, including all of the following:

a) The date which treatment with ruxolitinib was initiated;

b) A confirmation that the PBS restriction criteria for the relevant risk category was met at the time of initiation; and

c) The method by which ruxolitinib treatment was accessed at the time of initiation (e.g. through a compassionate use program).

Note Written applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Programs

Reply Paid 9826

HOBART TAS 7001

ruxolitinib 15 mg tablet, 56

10615Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5146.87	38.30	Jakavi [NV]

ruxolitinib 20 mg tablet, 56

10617T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5146.87	38.30	Jakavi [NV]

ruxolitinib 5 mg tablet, 56

10616R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*5146.87	38.30	Jakavi [NV]

■ TICARCILLIN + CLAVULANIC ACID**Restricted benefit**

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

ticarcillin 3 g + clavulanic acid 100 mg injection, 1 x 3.1 g vial

10125X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	*153.13	38.30	Timentin [AS]

■ TRANYLCPROMINE**Caution** This drug is an irreversible monoamine oxidase inhibitor.

tranylcypromine 10 mg tablet, 50

2444P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	57.60	38.30	Parnate [GH]

WARFARIN

Caution The listed brands have NOT been shown to be bioequivalent and should not be interchanged.

warfarin sodium 1 mg tablet, 50

2843P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	15.63	16.80	Coumadin [QA]	Marevan [FM]

warfarin sodium 2 mg tablet, 50

2209G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	15.94	17.11	Coumadin [QA]

warfarin sodium 3 mg tablet, 50

2844Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	15.87	17.04	Marevan [FM]

warfarin sodium 5 mg tablet, 50

2211J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	17.04	18.21	Coumadin [QA]	Marevan [FM]

Palliative Care

▪ FENTANYL

Caution The risk of drug dependence is high.

Note Shared Care Model:

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

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

Authority required

Breakthrough pain

Treatment Phase: Initial treatment for dose titration

Clinical criteria:

Patient must have cancer, **AND**

Patient must have pain directly attributable to cancer, **AND**

Patient must be assessed as receiving adequate management of their persistent pain with opioids, **AND**

Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; OR

The treatment must be used as short acting opioids are considered clinically inappropriate; OR

Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.

Treatment criteria:

Patient must be undergoing palliative care.

FENTANYL Lozenge 1200 micrograms (as citrate), 9

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
5405L NP	1	95.58	38.30	Actiq [TB]

FENTANYL Lozenge 1600 micrograms (as citrate), 9

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
5406M NP	1	95.58	38.30	Actiq [TB]

FENTANYL Lozenge 200 micrograms (as citrate), 9

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
5401G NP	1	95.58	38.30	Actiq [TB]

FENTANYL Lozenge 400 micrograms (as citrate), 9

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
5402H NP	1	95.58	38.30	Actiq [TB]

FENTANYL Lozenge 600 micrograms (as citrate), 9

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
5403J NP	1	95.58	38.30	Actiq [TB]

FENTANYL Lozenge 800 micrograms (as citrate), 9

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
5404K NP	1	95.58	38.30	Actiq [TB]

fentanyl 100 microgram tablet: sublingual, 10

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10601Y NP	1	86.44	38.30	Abstral [FK]

fentanyl 200 microgram tablet: sublingual, 10

10600X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	86.44	38.30	Abstral [FK]

fentanyl 300 microgram tablet: sublingual, 10

10606F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	86.44	38.30	Abstral [FK]

fentanyl 400 microgram tablet: sublingual, 10

10603C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	86.44	38.30	Abstral [FK]

fentanyl 600 microgram tablet: sublingual, 10

10604D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	86.44	38.30	Abstral [FK]

fentanyl 800 microgram tablet: sublingual, 10

10612M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	86.44	38.30	Abstral [FK]

■ FENTANYL

Caution The risk of drug dependence is high.

Note Shared Care Model:

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

Note For first continuing supply, applications for increased repeats for up to 3 months' supply may be authorised.

Note Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.

Note Telephone approvals are limited to 1 months' therapy.

Authority required

Breakthrough pain

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have cancer, **AND**

Patient must have pain directly attributable to cancer, **AND**

Patient must be assessed as receiving adequate management of their persistent pain with opioids, **AND**

Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; OR

The treatment must be used as short acting opioids are considered clinically inappropriate; OR

Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.

Treatment criteria:

Patient must be undergoing palliative care.

FENTANYL Lozenge 1200 micrograms (as citrate), 30

5411T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	*574.58	38.30	Actiq [TB]

FENTANYL Lozenge 1600 micrograms (as citrate), 30

5412W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	*574.58	38.30	Actiq [TB]

FENTANYL Lozenge 200 micrograms (as citrate), 30

5407N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	*574.58	38.30	Actiq [TB]

FENTANYL Lozenge 400 micrograms (as citrate), 30

5408P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	*574.58	38.30	Actiq [TB]

FENTANYL Lozenge 600 micrograms (as citrate), 30

5409Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	*574.58	38.30	Actiq [TB]

FENTANYL Lozenge 800 micrograms (as citrate), 30

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
5410R NP	2	*574.58	38.30	Actiq [TB]

fentanyl 100 microgram tablet: sublingual, 30

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10602B NP	2	*461.06	38.30	Abstral [FK]

fentanyl 200 microgram tablet: sublingual, 30

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10607G NP	2	*461.06	38.30	Abstral [FK]

fentanyl 300 microgram tablet: sublingual, 30

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10610K NP	2	*461.06	38.30	Abstral [FK]

fentanyl 400 microgram tablet: sublingual, 30

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10608H NP	2	*461.06	38.30	Abstral [FK]

fentanyl 600 microgram tablet: sublingual, 30

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10613N NP	2	*461.06	38.30	Abstral [FK]

fentanyl 800 microgram tablet: sublingual, 30

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10611L NP	2	*461.06	38.30	Abstral [FK]

Highly Specialised Drugs Program (Private Hospital)

▪ 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).

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

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

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

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

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, 1 x 30 mL vial

10192K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	4	..	5984.43	Soliris [XI]

▪ 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)

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

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

> Vaccinate patients with a meningococcal vaccine at least 2 weeks prior to receiving the first dose of eculizumab; revaccinate according to current medical guidelines for vaccine use

> Patients less than 2 years of age and those who are treated with eculizumab less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination.

Monitor patients for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary.

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

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

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

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have active and progressing thrombotic microangiopathy (TMA), **AND**

Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample taken prior to plasma exchange or infusion; or, if ADAMTS-13 activity was not collected prior to plasma exchange or infusion, patient must have platelet counts of greater than $30 \times 10^9/L$ and a serum creatinine of greater than 150 mol/L, **AND**

Patient must have a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days, **AND**

Patient must have clinical features of active organ damage or impairment, **AND**

Patient must not receive more than 4 weeks of treatment under this restriction.

Treatment criteria:

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

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

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

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

OR

(2) tissue biopsy confirming TMA in patients who do not have evidence of platelet consumption and haemolysis; **AND**

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

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

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

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

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 copy of a current Certificate of vaccination; and
- (5) A measurement of body weight at the time of application; and
- (6) The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion; the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the two weeks prior to collection of the ADAMTS-13 assay; and
- (7) In the case that a sample for ADAMTS-13 assay was not collected prior to plasma exchange or infusion, measurement of ADAMTS-13 activity must be taken 1-2 weeks following the last plasma exchange or infusion. The ADAMTS-13 result must be submitted to the Department of Human Services within 27 days of commencement of eculizumab treatment in order for the patient to be considered as eligible for further PBS-subsidised eculizumab treatment, under Initial treatment - balance of supply; and
- (8) A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days; and
- (9) Evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records. All tests must have been performed within one month of application; and
- (10) For all patients, a recent measurement of eGFR, platelets and two of either LDH, haptoglobin or schistocytes of no more than 1 week old at the time of application.

eculizumab 300 mg/30 mL injection, 1 x 30 mL vial

10182X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5984.43	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).

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

-
- Note** WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis)
> Vaccinate patients with a meningococcal vaccine at least 2 weeks prior to receiving the first dose of eculizumab; revaccinate according to current medical guidelines for vaccine use
> Patients less than 2 years of age and those who are treated with eculizumab less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination. Monitor patients for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary.
- Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.
- 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.
-

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 copy of a current Certificate of vaccination; and
- (4) A measurement of body weight at the time of application; and
- (5) An identified genetic mutation, if applicable; and
- (6) A family history of aHUS, if applicable; and
- (7) A history of multiple episodes of aHUS before commencing eculizumab treatment, if applicable; and
- (8) A history of kidney transplant, if applicable, (especially if required due to aHUS); and
- (9) An inclusion of the individual consequences of recurrent disease, if applicable; and
- (10) 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
- (11) 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
- (12) 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, 1 x 30 mL vial

10521R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	6	..	5984.43	Soliris [XI]

▪ ECULIZUMAB

Note WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis)
> Vaccinate patients with a meningococcal vaccine at least 2 weeks prior to receiving the first dose of eculizumab; revaccinate according to current medical guidelines for vaccine use
> Patients less than 2 years of age and those who are treated with eculizumab less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination. Monitor patients for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary.

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

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing treatment

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 copy of a current Certificate of vaccination; and

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

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

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

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

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

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

(10) 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

(11) 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

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

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

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%; OR

Patient must have severe TMA-related neurological impairment; OR

Patient must have severe TMA-related gastrointestinal impairment; OR

Patient must have severe TMA-related pulmonary impairment; OR

Patient must have grade 4 or 5 chronic kidney disease (eGFR of less than 30 ml/min), **AND**

Patient must not receive more than 24 weeks of treatment 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 copy of a current Certificate of vaccination; and

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

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

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

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

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

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

(10) A supporting statement with clinical evidence of severe TMA-related cardiomyopathy (including current LVEF result), neurological impairment, gastrointestinal impairment or pulmonary impairment; and

(11) 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

(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.

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

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

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 copy of a current Certificate of vaccination; 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 following the treatment break, 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 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;

(12) Evidence that the patient has had a treatment response to their previous treatment with eculizumab; 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 At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).

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

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

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

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 copy of a current Certificate of vaccination; and

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

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

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

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

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

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

(10) 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

(11) 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

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

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

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Grandfather eculizumab patient

Clinical criteria:

Patient must have had documented history of active and progressing thrombotic microangiopathy (TMA), **AND**

Patient must have had documented an ADAMTS-13 activity level consistent with a diagnosis of aHUS, **AND**

Patient must have received treatment with eculizumab for this condition prior to 1 December 2014, **AND**

Patient must have received treatment with eculizumab within the last 6 months at the time of application, **AND**

Patient must have demonstrated on-going treatment response as specified in the Extended Initial treatment criteria for PBS-subsidised treatment with eculizumab for this condition, if the patient has received adequate therapy in order to demonstrate response, **AND**

Patient must not have experienced treatment failure with eculizumab for this condition as specified in the Extended Initial treatment criteria for PBS-subsidised treatment with eculizumab for this condition, **AND**

Patient must have clinical features of active organ damage or impairment at the time of a diagnosis of aHUS episode that required treatment with eculizumab, **AND**

Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

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

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

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

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

OR

(2) tissue biopsy confirming TMA in patients who do not have evidence of platelet consumption and haemolysis; AND

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

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

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

(b) onset of TMA-related neurological impairment;

(c) onset of TMA-related cardiac impairment;

(d) onset of TMA-related gastrointestinal impairment;

(e) onset of TMA-related pulmonary impairment

A treatment response is defined as:

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

(2) One of the following:

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

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

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

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

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

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

The authority application must 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 initial PBS-subsidised eculizumab treatment; and

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

(4) A copy of a current Certificate of vaccination; and

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

(6) The result of ADAMTS-13 activity on a blood sample at the time this condition was diagnosed; and

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

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

(9) A history of multiple episodes of aHUS before commencing eculizumab treatment, 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) Evidence that the patient has previously received treatment with eculizumab for this condition within the last 6 months at the time of application; and

(13) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; or clinical reasons to justify the commencing of treatment with PBS-subsidised eculizumab; and

(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) A confirmed negative STEC (Shiga toxin-producing E.Coli) result if available at the time of diagnosis; or evidence that the diagnosis was not associated with an infection; and

(16) Where available in the week prior to commencing eculizumab results demonstrating:

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

(i) presence of schistocytes on blood film;

(ii) low or absent haptoglobin;

(iii) lactate dehydrogenase (LDH) above normal range;

OR

(b) tissue biopsy confirming TMA in patients who do not have evidence of platelet consumption and haemolysis; AND

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

- (a) kidney impairment as demonstrated by one of the following:
- (i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or
 - (ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or
 - (iii) a sCr of greater than the age-appropriate ULN in paediatric patients; or
 - (iv) a renal biopsy
- (b) onset of TMA-related neurological impairment;
- (c) onset of TMA-related cardiac impairment;
- (d) onset of TMA-related gastrointestinal impairment;
- (e) onset of TMA-related pulmonary impairment; and
- (17) Where available within one month prior to commencement of eculizumab, evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records.
- 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, 1 x 30 mL vial

10194M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	5984.43	Soliris [XI]

▪ **OCTREOTIDE**

Authority required

Acromegaly

Clinical criteria:

The condition must be controlled with octreotide immediate release injections, **AND**

The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), **AND**

The treatment must cease if IGF1 is not lower after 3 months of treatment.

In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

Authority required

Functional carcinoid tumour

Clinical criteria:

Patient must have achieved symptom control on octreotide immediate release injections, **AND**

The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

Authority required

Vasoactive intestinal peptide secreting tumour (VIPoma)

Clinical criteria:

Patient must have achieved symptom control on octreotide immediate release injections, **AND**

The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

octreotide 10 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

10566D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2660.65	Sandostatin LAR [NV]

octreotide 20 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

10549F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*3526.55	Sandostatin LAR [NV]

octreotide 30 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

10558Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*4401.85	Sandostatin LAR [NV]

▪ **THALIDOMIDE**

Caution Thalidomide is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

Note Patients receiving thalidomide under the PBS listing must be registered in the i-access risk management program.

Authority required

Multiple myeloma

thalidomide 100 mg capsule, 28

9684Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	*1726.93	Thalomid [CJ]

thalidomide 50 mg capsule, 28

6469L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	*1726.93	Thalomid [CJ]

Highly Specialised Drugs Program (Public Hospital)

▪ 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).

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

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

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

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

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, 1 x 30 mL vial

10190H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	4	..	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 four weeks of treatment, according to the specified dosage in the approved Product Information (PI)

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

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

> Vaccinate patients with a meningococcal vaccine at least 2 weeks prior to receiving the first dose of eculizumab; revaccinate according to current medical guidelines for vaccine use

> Patients less than 2 years of age and those who are treated with eculizumab less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination.

Monitor patients for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary.

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

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

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

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have active and progressing thrombotic microangiopathy (TMA), **AND**

Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample taken prior to plasma exchange or infusion; or, if ADAMTS-13 activity was not collected prior to plasma exchange or infusion, patient must have platelet counts of greater than $30 \times 10^9/L$ and a serum creatinine of greater than 150 mol/L, **AND**

Patient must have a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days, **AND**

Patient must have clinical features of active organ damage or impairment, **AND**

Patient must not receive more than 4 weeks of treatment under this restriction.

Treatment criteria:

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

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

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

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

OR

(2) tissue biopsy confirming TMA in patients who do not have evidence of platelet consumption and haemolysis; **AND**

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

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

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

(b) onset of TMA-related neurological impairment;

(c) onset of TMA-related cardiac impairment;

(d) onset of TMA-related gastrointestinal impairment;

(e) onset of TMA-related pulmonary impairment

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 copy of a current Certificate of vaccination; and
- (5) A measurement of body weight at the time of application; and
- (6) The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion; the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the two weeks prior to collection of the ADAMTS-13 assay; and
- (7) In the case that a sample for ADAMTS-13 assay was not collected prior to plasma exchange or infusion, measurement of ADAMTS-13 activity must be taken 1-2 weeks following the last plasma exchange or infusion. The ADAMTS-13 result must be submitted to the Department of Human Services within 27 days of commencement of eculizumab treatment in order for the patient to be considered as eligible for further PBS-subsidised eculizumab treatment, under Initial treatment - balance of supply; and
- (8) A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days; and
- (9) Evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records. All tests must have been performed within one month of application; and
- (10) For all patients, a recent measurement of eGFR, platelets and two of either LDH, haptoglobin or schistocytes of no more than 1 week old at the time of application.

eculizumab 300 mg/30 mL injection, 1 x 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).

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

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- Note** WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis)
> Vaccinate patients with a meningococcal vaccine at least 2 weeks prior to receiving the first dose of eculizumab; revaccinate according to current medical guidelines for vaccine use
> Patients less than 2 years of age and those who are treated with eculizumab less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination. Monitor patients for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary.
- Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.
- 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.
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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 copy of a current Certificate of vaccination; and
- (4) A measurement of body weight at the time of application; and
- (5) An identified genetic mutation, if applicable; and
- (6) A family history of aHUS, if applicable; and
- (7) A history of multiple episodes of aHUS before commencing eculizumab treatment, if applicable; and
- (8) A history of kidney transplant, if applicable, (especially if required due to aHUS); and
- (9) An inclusion of the individual consequences of recurrent disease, if applicable; and
- (10) 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
- (11) 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
- (12) 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, 1 x 30 mL vial

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

▪ ECULIZUMAB

Note WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis)
> Vaccinate patients with a meningococcal vaccine at least 2 weeks prior to receiving the first dose of eculizumab; revaccinate according to current medical guidelines for vaccine use
> Patients less than 2 years of age and those who are treated with eculizumab less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination. Monitor patients for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary.

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

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing treatment

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 copy of a current Certificate of vaccination; and

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

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

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

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

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

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

(10) 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

(11) 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

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

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

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%; OR

Patient must have severe TMA-related neurological impairment; OR

Patient must have severe TMA-related gastrointestinal impairment; OR

Patient must have severe TMA-related pulmonary impairment; OR

Patient must have grade 4 or 5 chronic kidney disease (eGFR of less than 30 ml/min), **AND**

Patient must not receive more than 24 weeks of treatment 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 copy of a current Certificate of vaccination; and

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

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

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

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

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

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

(10) A supporting statement with clinical evidence of severe TMA-related cardiomyopathy (including current LVEF result), neurological impairment, gastrointestinal impairment or pulmonary impairment; and

(11) 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

(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.

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

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

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 copy of a current Certificate of vaccination; 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 following the treatment break, 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 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;

(12) Evidence that the patient has had a treatment response to their previous treatment with eculizumab; 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 At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).

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

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

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

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 copy of a current Certificate of vaccination; and

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

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

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

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

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

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

(10) 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

(11) 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

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

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

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Grandfather eculizumab patient

Clinical criteria:

Patient must have had documented history of active and progressing thrombotic microangiopathy (TMA), **AND**

Patient must have had documented an ADAMTS-13 activity level consistent with a diagnosis of aHUS, **AND**

Patient must have received treatment with eculizumab for this condition prior to 1 December 2014, **AND**

Patient must have received treatment with eculizumab within the last 6 months at the time of application, **AND**

Patient must have demonstrated on-going treatment response as specified in the Extended Initial treatment criteria for PBS-subsidised treatment with eculizumab for this condition, if the patient has received adequate therapy in order to demonstrate response, **AND**

Patient must not have experienced treatment failure with eculizumab for this condition as specified in the Extended Initial treatment criteria for PBS-subsidised treatment with eculizumab for this condition, **AND**

Patient must have clinical features of active organ damage or impairment at the time of a diagnosis of aHUS episode that required treatment with eculizumab, **AND**

Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

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

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

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

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

OR

(2) tissue biopsy confirming TMA in patients who do not have evidence of platelet consumption and haemolysis; AND

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

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

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

(b) onset of TMA-related neurological impairment;

(c) onset of TMA-related cardiac impairment;

(d) onset of TMA-related gastrointestinal impairment;

(e) onset of TMA-related pulmonary impairment

A treatment response is defined as:

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

(2) One of the following:

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

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

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

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

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

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

The authority application must 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 initial PBS-subsidised eculizumab treatment; and

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

(4) A copy of a current Certificate of vaccination; and

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

(6) The result of ADAMTS-13 activity on a blood sample at the time this condition was diagnosed; and

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

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

(9) A history of multiple episodes of aHUS before commencing eculizumab treatment, 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) Evidence that the patient has previously received treatment with eculizumab for this condition within the last 6 months at the time of application; and

(13) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; or clinical reasons to justify the commencing of treatment with PBS-subsidised eculizumab; and

(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) A confirmed negative STEC (Shiga toxin-producing E.Coli) result if available at the time of diagnosis; or evidence that the diagnosis was not associated with an infection; and

(16) Where available in the week prior to commencing eculizumab results demonstrating:

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

(i) presence of schistocytes on blood film;

(ii) low or absent haptoglobin;

(iii) lactate dehydrogenase (LDH) above normal range;

OR

(b) tissue biopsy confirming TMA in patients who do not have evidence of platelet consumption and haemolysis; AND

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

- (a) kidney impairment as demonstrated by one of the following:
- (i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or
 - (ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or
 - (iii) a sCr of greater than the age-appropriate ULN in paediatric patients; or
 - (iv) a renal biopsy
- (b) onset of TMA-related neurological impairment;
- (c) onset of TMA-related cardiac impairment;
- (d) onset of TMA-related gastrointestinal impairment;
- (e) onset of TMA-related pulmonary impairment; and
- (17) Where available within one month prior to commencement of eculizumab, evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records.
- 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, 1 x 30 mL vial

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

■ **OCTREOTIDE**

Authority required (STREAMLINED)

5900

Acromegaly

Clinical criteria:

The condition must be controlled with octreotide immediate release injections, **AND**

The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), **AND**

The treatment must cease if IGF1 is not lower after 3 months of treatment.

In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

Authority required (STREAMLINED)

5901

Functional carcinoid tumour

Clinical criteria:

Patient must have achieved symptom control on octreotide immediate release injections, **AND**

The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

Authority required (STREAMLINED)

5906

Vasoactive intestinal peptide secreting tumour (VIPoma)

Clinical criteria:

Patient must have achieved symptom control on octreotide immediate release injections, **AND**

The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

octreotide 10 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

10543X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2613.72	Sandostatin LAR [NV]

octreotide 20 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

10533J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*3479.62	Sandostatin LAR [NV]

octreotide 30 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

10550G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*4354.92	Sandostatin LAR [NV]

▪ **THALIDOMIDE**

Caution Thalidomide is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

Note Patients receiving thalidomide under the PBS listing must be registered in the i-access risk management program.

Authority required (STREAMLINED)

5914

Multiple myeloma

thalidomide 100 mg capsule, 28

9667T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	*1680.00	Thalomid [CJ]

thalidomide 50 mg capsule, 28

9566L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	*1680.00	Thalomid [CJ]

Repatriation Pharmaceutical Benefits Scheme

▪ BANDAGE CALICO

bandage calico large bandage: triangular, 1 bandage

4717G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	16.43	6.20	Handy 36361414 [BV]

▪ BANDAGE COMPRESSION

Note Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

BANDAGE-COMPRESSION Bandage, short stretch, 8 cm x 2.6 m, 1

4654Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	*76.23	6.20	Comprilan 01027-00 [BV]

bandage compression 10 cm x 3 m bandage: high stretch, 1 bandage

4748X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	*70.88	6.20	Surepress 650947 [CC]
			..	*149.18	6.20	Tensopress 71723-00 [BV]

▪ BANDAGE RETENTION COHESIVE LIGHT

bandage retention cohesive light 10 cm x 2 m bandage, 1

4662J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	*32.81	6.20	Handygauze Cohesive 8635 [BV]

bandage retention cohesive light 2.5 cm x 2 m bandage, 2

4718H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	16.56	6.20	Handygauze Cohesive 8631 [BV]

bandage retention cohesive light 6 cm x 2 m bandage, 1

4719J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	*18.95	6.20	Handygauze Cohesive 8633 [BV]

▪ BANDAGE RETENTION COTTON CREPE

bandage retention cotton crepe 10 cm x 2.3 m bandage, 1

4729X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	*26.91	6.20	Telfa 8254F [KE]
			..	*32.35	6.20	Tensocrepe 36301001 [BV]

bandage retention cotton crepe 5 cm x 2.3 m bandage, 1

4727T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	*19.99	6.20	Telfa 8252F [KE]
			..	*22.65	6.20	Tensocrepe 36300501 [BV]

bandage retention cotton crepe 7.5 cm x 2.3 m bandage, 1

4728W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	*24.17	6.20	Telfa 8253F [KE]
			..	*27.21	6.20	Tensocrepe 36307501 [BV]

▪ BROMAZEPAM

Note This drug should not be used as the first line of treatment.

Note Other PBS-listed benzodiazepines should have been adequately tried and found to be ineffective or inappropriate.

Note Authorities for increased quantities and/or repeats may be granted to patients with terminal disease, and other patients who have been shown to be dependent on this item by an unsuccessful attempt at gradual withdrawal.

Authority required

Terminal disease

Clinical criteria:

The treatment must be for the short-term, **AND**

Patient must be receiving palliative care.

Authority required

Refractory phobic or anxiety states

Clinical criteria:

The treatment must be for the short-term.

bromazepam 3 mg tablet, 30

4150K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	*30.49	6.20	Lexotan [RO]

bromazepam 6 mg tablet, 30

4151L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	*36.23	6.20	Lexotan [RO]

▪ **DRESSING GAUZE ABSORBENT**

dressing gauze absorbent 10 cm x 10 cm pad, 100

4708T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	31.75	6.20	Handy 71117-06 [BV]

dressing gauze absorbent 5 cm x 5 cm pad, 100

4707R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	18.02	6.20	Handy 71117-05 [BV]

▪ **FLUNITRAZEPAM**

Note This drug should not be used as the first line of treatment.

Note Other PBS-listed benzodiazepines should have been adequately tried and found to be ineffective or inappropriate.

Note Authorities for increased quantities and/or repeats may be granted to patients with terminal disease, and other patients who have been shown to be dependent on this item by an unsuccessful attempt at gradual withdrawal.

Authority required

Terminal disease

Clinical criteria:

The treatment must be for the short-term, **AND**

Patient must be receiving palliative care.

Authority required

Refractory phobic or anxiety states

Clinical criteria:

The treatment must be for the short-term.

flunitrazepam 1 mg tablet, 30

4216X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	18.33	6.20	Hypnodorm [AF]

▪ **GAUZE AND COTTON TISSUE COMBINE ROLL**

gauze and cotton tissue combine roll 9 cm x 10 m roll: wrapped pack, 1 pack

4767X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	15.11	6.20	BSN 2902165 [BV]

▪ **TAPE PLASTER ADHESIVE ELASTIC**

tape plaster adhesive elastic 2.5 cm x 2.5 m tape, 1 roll

4780N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	16.95	6.20	Leukoplast 01071-00 [BV]

tape plaster adhesive elastic 5 cm x 2.5 m tape, 1 roll

4781P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	22.89	6.20	Leukoplast 01072-00 [BV]

tape plaster adhesive elastic 7.5 cm x 2.5 m tape, 1 roll

4782Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	26.57	6.20	Leukoplast 01073-00 [BV]

▪ TAPE PLASTER ADHESIVE HYPOALLERGENIC**tape plaster adhesive hypoallergenic 1.25 cm x 5 m tape, 1 roll**

4783R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	14.36	6.20	Leukopor 2471 [BV]

tape plaster adhesive hypoallergenic 1.25 cm x 5 m tape, 1 roll

4785W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	14.65	6.20	Leukosilk 1021 [BV]

tape plaster adhesive hypoallergenic 2.5 cm x 5 m tape, 1 roll

4787Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	17.30	6.20	Leukosilk 1022 [BV]

tape plaster adhesive hypoallergenic 2.5 cm x 5 m tape, 1 roll

4794H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	16.77	6.20	Leukopor 2472 [BV]

tape plaster adhesive hypoallergenic 5 cm x 5 m stretch tape, 1 roll

4788B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	19.80	6.20	Leukoflex 1124 [BV]

tape plaster adhesive hypoallergenic 5 cm x 5 m stretch tape, 1 roll

4789C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	21.12	6.20	Leukosilk 1024 [BV]

tape plaster adhesive hypoallergenic 5 cm x 5 m stretch tape, 1 roll

4790D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	20.29	6.20	Leukopor 2474 [BV]