



Australian Government

Department of Health



Schedule of Pharmaceutical Benefits

Summary of Changes

Effective 1 June 2022



Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 June 2022 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	\$7.78
	Dangerous drug fee	\$4.82
	Extemporaneously-prepared	\$9.82
	Allowable additional patient charge*	\$4.54
Additional Fees (for safety net prices):	Ready-prepared	\$1.30
	Extemporaneously-prepared	\$1.67
Patient Co-payments:	General	\$42.50
	Concessional	\$6.80
Safety Net Thresholds:	General	\$1542.10
	Concessional	\$326.40
Safety Net Card Issue Fee:		\$10.65

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

Summary of Changes

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 June 2022. 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

12999E **VENETOCLAX**, venetoclax 10 mg tablet, 2 (*Venclexta*)

Addition – Brand

8697R *Adrenaline Jr Viatris, AF* – **ADRENALINE (EPINEPHRINE)**, adrenaline (epinephrine) 150 microgram/0.3 mL injection, 0.3 mL pen device

8698T *Adrenaline Viatris, AF* – **ADRENALINE (EPINEPHRINE)**, adrenaline (epinephrine) 300 microgram/0.3 mL injection, 0.3 mL pen device

2417F *Amitriptyline Viatris 10, AL* – **AMITRIPTYLINE**, amitriptyline hydrochloride 10 mg tablet, 50

2418G *Amitriptyline Viatris 25, AL* – **AMITRIPTYLINE**, amitriptyline hydrochloride 25 mg tablet, 50

2429W *Amitriptyline Viatris 50, AL* – **AMITRIPTYLINE**, amitriptyline hydrochloride 50 mg tablet, 50

8358X *Clopidogrel Lupin, GQ* – **CLOPIDOGREL**, clopidogrel 75 mg tablet, 28

8420E *Hydromorphone-hameln, HW* – **HYDROMORPHONE**, hydromorphone hydrochloride 2 mg/mL injection, 5 x 1 mL ampoules

8421F *Hydromorphone-hameln-HP, HW* – **HYDROMORPHONE**, hydromorphone hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules

11762C *Gilmat, CR* – **IMATINIB**, imatinib 100 mg tablet, 60

9178C *Gilmat, CR* – **IMATINIB**, imatinib 100 mg tablet, 60

11785G *Gilmat, CR* – **IMATINIB**, imatinib 400 mg tablet, 30

9179D *Gilmat, CR* – **IMATINIB**, imatinib 400 mg tablet, 30

9333F *Lacoress, LR* – **LACOSAMIDE**, lacosamide 50 mg tablet, 14

9334G *Lacoress, LR* – **LACOSAMIDE**, lacosamide 100 mg tablet, 14

9335H *Lacoress, LR* – **LACOSAMIDE**, lacosamide 100 mg tablet, 56

9336J *Lacoress, LR* – **LACOSAMIDE**, lacosamide 150 mg tablet, 14

9337K *Lacoress, LR* – **LACOSAMIDE**, lacosamide 150 mg tablet, 56

9338L *Lacoress, LR* – **LACOSAMIDE**, lacosamide 200 mg tablet, 56

8732N *Topreloc-XL, CR* – **METOPROLOL SUCCINATE**, METOPROLOL SUCCINATE Tablet 23.75 mg (controlled release), 15

8733P *Topreloc-XL, CR* – **METOPROLOL SUCCINATE**, METOPROLOL SUCCINATE Tablet 47.5 mg (controlled release), 30

8734Q *Topreloc-XL, CR* – **METOPROLOL SUCCINATE**, METOPROLOL SUCCINATE Tablet 95 mg (controlled release), 30

8735R *Topreloc-XL, CR* – **METOPROLOL SUCCINATE**, METOPROLOL SUCCINATE Tablet 190 mg (controlled release), 30

2339D *Spironolactone Viatris 25, AL* – **SPIRONOLACTONE**, spironolactone 25 mg tablet, 100

2340E *Spirolactone Viatris 100, AL* – **SPIRONOLACTONE**, spironolactone 100 mg tablet, 100

Addition – Equivalence Indicator

11624T *Venclexa, VE* – **VENETOCLAX**, venetoclax 10 mg tablet, 14

Addition – Note

12290W **ESOMEPRAZOLE**, esomeprazole 40 mg enteric capsule, 30 (*Noxicid Caps*)

12283L **ESOMEPRAZOLE**, esomeprazole 40 mg enteric tablet, 30 (*APO-Esomeprazole, Esomeprazole Apotex, Esomeprazole GH, Esomeprazole GxP, Esomeprazole Mylan, Esomeprazole RBX, Esomeprazole SZ, Esomeprazole Sandoz, Esopreze, NOUMED ESOMEPRAZOLE, Nexazole, Nexium, Nexole*)

11624T **VENETOCLAX**, venetoclax 10 mg tablet, 14 (*Venclexa*)

Deletions

Deletion – Item

11467M **HYDROMORPHONE**, hydromorphone hydrochloride 1 mg/mL oral liquid, 200 mL (*Dilaudid*)

11479E **HYDROMORPHONE**, hydromorphone hydrochloride 1 mg/mL oral liquid, 200 mL (*Dilaudid*)

Deletion – Brand

8697R *Adrenaline Jr Mylan, AF* – **ADRENALINE (EPINEPHRINE)**, adrenaline (epinephrine) 150 microgram/0.3 mL injection, 0.3 mL pen device

8698T *Adrenaline Mylan, AF* – **ADRENALINE (EPINEPHRINE)**, adrenaline (epinephrine) 300 microgram/0.3 mL injection, 0.3 mL pen device

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

9315G *Candesartan HCT GH 32/25, GQ* – **CANDESARTAN + HYDROCHLOROTHIAZIDE**, candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30

8439E *APO-Celecoxib, TX* – **CELECOXIB**, celecoxib 100 mg capsule, 60

8439E *Celecoxib BTC, JB* – **CELECOXIB**, celecoxib 100 mg capsule, 60

8439E *GenRx Celecoxib, GX* – **CELECOXIB**, celecoxib 100 mg capsule, 60

8440F *APO-Celecoxib, TX* – **CELECOXIB**, celecoxib 200 mg capsule, 30

8440F *Celecoxib BTC, JB* – **CELECOXIB**, celecoxib 200 mg capsule, 30

8440F *GenRx Celecoxib, GX* – **CELECOXIB**, celecoxib 200 mg capsule, 30

9354H *Clopidogrel APOTEX, GX* – **CLOPIDOGREL**, clopidogrel 75 mg tablet, 28

9296G *CoPlavix, SW* – **CLOPIDOGREL + ASPIRIN**, clopidogrel 75 mg + aspirin 100 mg tablet, 30

9106G *Frakas, RW* – **DOXYCYCLINE**, doxycycline 50 mg tablet, 25

1182F *Fosipril 10, RW* – **FOSINOPRIL**, fosinopril sodium 10 mg tablet, 30

1183G *Fosipril 20, RW* – **FOSINOPRIL**, fosinopril sodium 20 mg tablet, 30

8450R *APO-Glimepiride, TX* – **GLIMEPIRIDE**, glimepiride 1 mg tablet, 30

8451T *APO-Glimepiride, TX* – **GLIMEPIRIDE**, glimepiride 2 mg tablet, 30

8533D *APO-Glimepiride, TX* – **GLIMEPIRIDE**, glimepiride 3 mg tablet, 30

8452W *APO-Glimepiride, TX* – **GLIMEPIRIDE**, glimepiride 4 mg tablet, 30

8452W *Dimirel, AV* – **GLIMEPIRIDE**, glimepiride 4 mg tablet, 30

8404H *KSART HCT 150/12.5, RW* – **IRBESARTAN + HYDROCHLOROTHIAZIDE**, irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30

8405J *KSART HCT 300/12.5, RW* – **IRBESARTAN + HYDROCHLOROTHIAZIDE**, irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30

2136K *KSART HCT 300/25, RW* – **IRBESARTAN + HYDROCHLOROTHIAZIDE**, irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30

1558B *GenRx Isosorbide Mononitrate, GX* – **ISOSORBIDE MONONITRATE**, isosorbide mononitrate 60 mg modified release tablet, 30

5553G	<i>Latanoprost/Timolol Sandoz 50/5, SZ</i> – LATANOPROST + TIMOLOL , latanoprost 0.005% + timolol 0.5% eye drops, 2.5 mL
8895E	<i>Latanoprost/Timolol Sandoz 50/5, SZ</i> – LATANOPROST + TIMOLOL , latanoprost 0.005% + timolol 0.5% eye drops, 2.5 mL
8534E	<i>Lercan, RW</i> – LERCANIDIPINE , lercanidipine hydrochloride 10 mg tablet, 28
8679T	<i>Lercan, RW</i> – LERCANIDIPINE , lercanidipine hydrochloride 20 mg tablet, 28
8245Y	<i>APO-Letrozole, TX</i> – LETROZOLE , letrozole 2.5 mg tablet, 30
1636D	<i>Flagyl, SW</i> – METRONIDAZOLE , metronidazole 200 mg tablet, 21
3339R	<i>Flagyl, SW</i> – METRONIDAZOLE , metronidazole 200 mg tablet, 21
8627C	<i>APO-Montelukast, TX</i> – MONTELUKAST , montelukast 4 mg chewable tablet, 28
8627C	<i>Respikast 4, RW</i> – MONTELUKAST , montelukast 4 mg chewable tablet, 28
8628D	<i>APO-Montelukast, TX</i> – MONTELUKAST , montelukast 5 mg chewable tablet, 28
8628D	<i>Respikast 5, RW</i> – MONTELUKAST , montelukast 5 mg chewable tablet, 28
8650G	<i>APO-Mycophenolate, TX</i> – MYCOPHENOLATE , mycophenolate mofetil 500 mg tablet, 50
1692C	<i>ARX-Nitrofurantoin, XT</i> – NITROFURANTOIN , nitrofurantoin 50 mg capsule, 30
1693D	<i>ARX-Nitrofurantoin, XT</i> – NITROFURANTOIN , nitrofurantoin 100 mg capsule, 30
3010K	<i>GenRx Norfloxacin, GX</i> – NORFLOXACIN , norfloxacin 400 mg tablet, 14
8170B	<i>APO-Olanzapine, TX</i> – OLANZAPINE , olanzapine 2.5 mg tablet, 28
8185T	<i>APO-Olanzapine, TX</i> – OLANZAPINE , olanzapine 5 mg tablet, 28
8186W	<i>APO-Olanzapine, TX</i> – OLANZAPINE , olanzapine 7.5 mg tablet, 28
8187X	<i>APO-Olanzapine, TX</i> – OLANZAPINE , olanzapine 10 mg tablet, 28
8039D	<i>Oxybutynin Sandoz, SZ</i> – OXYBUTYNIN , oxybutynin hydrochloride 5 mg tablet, 100
8385H	<i>Novacodone, HX</i> – OXYCODONE , oxycodone hydrochloride 10 mg modified release tablet, 28
8386J	<i>Novacodone, HX</i> – OXYCODONE , oxycodone hydrochloride 20 mg modified release tablet, 28
8387K	<i>Novacodone, HX</i> – OXYCODONE , oxycodone hydrochloride 40 mg modified release tablet, 28
8388L	<i>Novacodone, HX</i> – OXYCODONE , oxycodone hydrochloride 80 mg modified release tablet, 28
3050M	<i>Perindopril APOTEX, TY</i> – PERINDOPRIL , perindopril erbumine 2 mg tablet, 30
3051N	<i>Perindopril APOTEX, TY</i> – PERINDOPRIL , perindopril erbumine 4 mg tablet, 30
8704D	<i>Perindopril APOTEX, TY</i> – PERINDOPRIL , perindopril erbumine 8 mg tablet, 30
2348N	<i>BTC PREGABALIN, JB</i> – PREGABALIN , pregabalin 25 mg capsule, 56
2348N	<i>Pregabalin APOTEX, GX</i> – PREGABALIN , pregabalin 25 mg capsule, 56
2335X	<i>BTC PREGABALIN, JB</i> – PREGABALIN , pregabalin 75 mg capsule, 56
2335X	<i>Pregabalin APOTEX, GX</i> – PREGABALIN , pregabalin 75 mg capsule, 56
2355Y	<i>BTC PREGABALIN, JB</i> – PREGABALIN , pregabalin 150 mg capsule, 56
2355Y	<i>Pregabalin APOTEX, GX</i> – PREGABALIN , pregabalin 150 mg capsule, 56
2363J	<i>BTC PREGABALIN, JB</i> – PREGABALIN , pregabalin 300 mg capsule, 56
2363J	<i>Pregabalin APOTEX, GX</i> – PREGABALIN , pregabalin 300 mg capsule, 56
8456C	<i>APO-Quetiapine, TX</i> – QUETIAPINE , quetiapine 25 mg tablet, 60
8456C	<i>Quetiapine Sandoz, SZ</i> – QUETIAPINE , quetiapine 25 mg tablet, 60
9202H	<i>APO-Quetiapine XR, TX</i> – QUETIAPINE , quetiapine 50 mg modified release tablet, 60
8457D	<i>APO-Quetiapine, TX</i> – QUETIAPINE , quetiapine 100 mg tablet, 90
8457D	<i>Quetiapine Sandoz, SZ</i> – QUETIAPINE , quetiapine 100 mg tablet, 90
8458E	<i>APO-Quetiapine, TX</i> – QUETIAPINE , quetiapine 200 mg tablet, 60
8458E	<i>Quetiapine Sandoz, SZ</i> – QUETIAPINE , quetiapine 200 mg tablet, 60
9203J	<i>APO-Quetiapine XR, TX</i> – QUETIAPINE , quetiapine 200 mg modified release tablet, 60

8580N	<i>APO-Quetiapine, TX – QUETIAPINE</i> , quetiapine 300 mg tablet, 60
8580N	<i>Quetiapine Sandoz, SZ – QUETIAPINE</i> , quetiapine 300 mg tablet, 60
9204K	<i>APO-Quetiapine XR, TX – QUETIAPINE</i> , quetiapine 300 mg modified release tablet, 60
9205L	<i>APO-Quetiapine XR, TX – QUETIAPINE</i> , quetiapine 400 mg modified release tablet, 60
2590H	<i>BTC Rosuvastatin, JB – ROSUVASTATIN</i> , rosuvastatin 5 mg tablet, 30
2606E	<i>BTC Rosuvastatin, JB – ROSUVASTATIN</i> , rosuvastatin 5 mg tablet, 30
2584B	<i>BTC Rosuvastatin, JB – ROSUVASTATIN</i> , rosuvastatin 10 mg tablet, 30
2628H	<i>BTC Rosuvastatin, JB – ROSUVASTATIN</i> , rosuvastatin 10 mg tablet, 30
2574L	<i>BTC Rosuvastatin, JB – ROSUVASTATIN</i> , rosuvastatin 20 mg tablet, 30
2609H	<i>BTC Rosuvastatin, JB – ROSUVASTATIN</i> , rosuvastatin 20 mg tablet, 30
2594M	<i>BTC Rosuvastatin, JB – ROSUVASTATIN</i> , rosuvastatin 40 mg tablet, 30
2636R	<i>BTC Rosuvastatin, JB – ROSUVASTATIN</i> , rosuvastatin 40 mg tablet, 30
2339D	<i>Spironolactone Mylan 25, AL – SPIRONOLACTONE</i> , spironolactone 25 mg tablet, 100
2340E	<i>Spironolactone Mylan 100, AL – SPIRONOLACTONE</i> , spironolactone 100 mg tablet, 100
10173K	<i>Voriconazole APO, GX – VORICONAZOLE</i> , voriconazole 50 mg tablet, 56
10173K	<i>Voriconazole APOTEX, TX – VORICONAZOLE</i> , voriconazole 50 mg tablet, 56
9363T	<i>Voriconazole APO, GX – VORICONAZOLE</i> , voriconazole 50 mg tablet, 56
9363T	<i>Voriconazole APOTEX, TX – VORICONAZOLE</i> , voriconazole 50 mg tablet, 56
10198R	<i>Voriconazole APO, GX – VORICONAZOLE</i> , voriconazole 200 mg tablet, 56
10198R	<i>Voriconazole APOTEX, TX – VORICONAZOLE</i> , voriconazole 200 mg tablet, 56
9364W	<i>Voriconazole APO, GX – VORICONAZOLE</i> , voriconazole 200 mg tablet, 56
9364W	<i>Voriconazole APOTEX, TX – VORICONAZOLE</i> , voriconazole 200 mg tablet, 56
9388D	<i>APO-Zonisamide, TX – ZONISAMIDE</i> , zonisamide 25 mg capsule, 56
9389E	<i>APO-Zonisamide, TX – ZONISAMIDE</i> , zonisamide 50 mg capsule, 56
9390F	<i>APO-Zonisamide, TX – ZONISAMIDE</i> , zonisamide 100 mg capsule, 56

Deletion – Equivalence Indicator

8039D	<i>Ditropan, SW – OXYBUTYNIN</i> , oxybutynin hydrochloride 5 mg tablet, 100
9388D	<i>Zonegran, GH – ZONISAMIDE</i> , zonisamide 25 mg capsule, 56
9389E	<i>Zonegran, GH – ZONISAMIDE</i> , zonisamide 50 mg capsule, 56
9390F	<i>Zonegran, GH – ZONISAMIDE</i> , zonisamide 100 mg capsule, 56

Deletion – Note

11385F	RIBOCICLIB , ribociclib 200 mg tablet, 21 (<i>Kisqali</i>)
11386G	RIBOCICLIB , ribociclib 200 mg tablet, 63 (<i>Kisqali</i>)
11397W	RIBOCICLIB , ribociclib 200 mg tablet, 42 (<i>Kisqali</i>)
12307R	SECUKINUMAB , secukinumab 150 mg/mL injection, 1 mL pen device (<i>Cosentyx</i>)
12670W	TERIPARATIDE , teriparatide 250 microgram/mL injection, 2.4 mL cartridge (<i>Terrosa</i>)

Deletion – Restriction

11385F	RIBOCICLIB , ribociclib 200 mg tablet, 21 (<i>Kisqali</i>)
11386G	RIBOCICLIB , ribociclib 200 mg tablet, 63 (<i>Kisqali</i>)
11397W	RIBOCICLIB , ribociclib 200 mg tablet, 42 (<i>Kisqali</i>)
12307R	SECUKINUMAB , secukinumab 150 mg/mL injection, 1 mL pen device (<i>Cosentyx</i>)

Alterations

Alteration – Item Description

From

12931N	MYCOBACTERIUM BOVIS (BACILLUS CALMETTE AND GUERIN (BCG)) DANISH 1331 STRAIN , Mycobacterium bovis (Bacillus Calmette and Guerin (BCG)) Danish 1331 strain 250 million CFU 30 mg, 4 vials (<i>BCG Culture SSI</i>)
To	
12931N	MYCOBACTERIUM BOVIS BCG DANISH STRAIN , Mycobacterium bovis BCG Danish strain 30 mg injection, 4 vials (<i>BCG Culture SSI</i>)
From	
1131M	MYCOBACTERIUM BOVIS (BACILLUS CALMETTE AND GUERIN (BCG)) TICE STRAIN , Mycobacterium bovis (Bacillus Calmette and Guerin (BCG)) Tice strain 500 million CFU injection, 3 vials (<i>OncoTICE</i>)
To	
1131M	MYCOBACTERIUM BOVIS BCG TICE STRAIN , Mycobacterium bovis BCG Tice strain 500 million CFU injection, 3 vials (<i>OncoTICE</i>)

Alteration – Note

12921C	OLAPARIB , olaparib 100 mg tablet, 56 (<i>Lynparza</i>)
12932P	OLAPARIB , olaparib 100 mg tablet, 56 (<i>Lynparza</i>)
12913P	OLAPARIB , olaparib 150 mg tablet, 56 (<i>Lynparza</i>)
12929L	OLAPARIB , olaparib 150 mg tablet, 56 (<i>Lynparza</i>)
8385H	OXYCODONE , oxycodone hydrochloride 10 mg modified release tablet, 28 (<i>OxyContin, Oxycodone Sandoz</i>)
8386J	OXYCODONE , oxycodone hydrochloride 20 mg modified release tablet, 28 (<i>OxyContin, Oxycodone Sandoz</i>)
8387K	OXYCODONE , oxycodone hydrochloride 40 mg modified release tablet, 28 (<i>OxyContin, Oxycodone Sandoz</i>)
8388L	OXYCODONE , oxycodone hydrochloride 80 mg modified release tablet, 28 (<i>OxyContin, Oxycodone Sandoz</i>)
12297F	SECUKINUMAB , secukinumab 150 mg/mL injection, 1 mL pen device (<i>Cosentyx</i>)

Alteration – Restriction

12297F	SECUKINUMAB , secukinumab 150 mg/mL injection, 1 mL pen device (<i>Cosentyx</i>)
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Advance Notices

1 July 2022

Deletion – Brand

1052J	<i>GenRx Aciclovir, GX</i> – ACICLOVIR , aciclovir 800 mg tablet, 35
1555W	<i>GenRx Aciclovir, GX</i> – ACICLOVIR , aciclovir 200 mg tablet, 50
8511Y	<i>Alendro Once Weekly, RW</i> – ALENDRONATE , alendronate 70 mg tablet, 4
2343H	<i>Rithmik 200, RW</i> – AMIODARONE , amiodarone hydrochloride 200 mg tablet, 30
2751T	<i>BTC Amlodipine, JB</i> – AMLODIPINE , amlodipine 5 mg tablet, 30
2752W	<i>BTC Amlodipine, JB</i> – AMLODIPINE , amlodipine 10 mg tablet, 30
8213G	<i>Torvastat 10, RW</i> – ATORVASTATIN , atorvastatin 10 mg tablet, 30
8214H	<i>Torvastat 20, RW</i> – ATORVASTATIN , atorvastatin 20 mg tablet, 30
8215J	<i>Torvastat 40, RW</i> – ATORVASTATIN , atorvastatin 40 mg tablet, 30
8521L	<i>Torvastat 80, RW</i> – ATORVASTATIN , atorvastatin 80 mg tablet, 30
9230T	<i>Torvastat 10, RW</i> – ATORVASTATIN , atorvastatin 10 mg tablet, 30
9231W	<i>Torvastat 20, RW</i> – ATORVASTATIN , atorvastatin 20 mg tablet, 30
9232X	<i>Torvastat 40, RW</i> – ATORVASTATIN , atorvastatin 40 mg tablet, 30
9233Y	<i>Torvastat 80, RW</i> – ATORVASTATIN , atorvastatin 80 mg tablet, 30
1780Q	<i>Dantrium, PF</i> – DANTROLENE , dantrolene sodium hemiheptahydrate 50 mg capsule, 100
8533D	<i>Dimirel, AV</i> – GLIMEPIRIDE , glimepiride 3 mg tablet, 30
8561N	<i>APO-Meloxicam, TX</i> – MELOXICAM , meloxicam 7.5 mg tablet, 30
8562P	<i>APO-Meloxicam, TX</i> – MELOXICAM , meloxicam 15 mg tablet, 30
8621R	<i>Risedro once a week, RW</i> – RISEDRONATE , risedronate sodium 35 mg tablet, 4
8144P	<i>Sumatriptan Sandoz, SZ</i> – SUMATRIPTAN , sumatriptan 50 mg tablet, 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 TACROLIMUS APOTEX, TX – **TACROLIMUS**, tacrolimus 5 mg capsule, 50

1 September 2022

Deletion – Brand

8451T Dimirel, AV – **GLIMEPIRIDE**, glimepiride 2 mg tablet, 30

1 November 2022

Deletion – Brand

10375C Nutrini Peptisorb, SB – **TRIGLYCERIDES MEDIUM CHAIN FORMULA**, triglycerides medium chain formula oral liquid, 8 x 500 mL pouches

Palliative Care

Additions

Addition – Brand

12493M Hydromorphone-hameln, HW – **HYDROMORPHONE**, hydromorphone hydrochloride 2 mg/mL injection, 5 x 1 mL ampoules

12531M Hydromorphone-hameln-HP, HW – **HYDROMORPHONE**, hydromorphone hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules

Deletions

Deletion – Item

12485D **HYDROMORPHONE**, hydromorphone hydrochloride 1 mg/mL oral liquid, 200 mL (*Dilaudid*)

Deletion – Brand

12518W Novacodone, HX – **OXYCODONE**, oxycodone hydrochloride 10 mg modified release tablet, 28

12510K Novacodone, HX – **OXYCODONE**, oxycodone hydrochloride 20 mg modified release tablet, 28

12525F Novacodone, HX – **OXYCODONE**, oxycodone hydrochloride 40 mg modified release tablet, 28

12527H Novacodone, HX – **OXYCODONE**, oxycodone hydrochloride 80 mg modified release tablet, 28

Alterations

Alteration – Note

12518W **OXYCODONE**, oxycodone hydrochloride 10 mg modified release tablet, 28 (*OxyContin*, *Oxycodone Sandoz*)

12510K **OXYCODONE**, oxycodone hydrochloride 20 mg modified release tablet, 28 (*OxyContin*, *Oxycodone Sandoz*)

12525F **OXYCODONE**, oxycodone hydrochloride 40 mg modified release tablet, 28 (*OxyContin*, *Oxycodone Sandoz*)

12527H **OXYCODONE**, oxycodone hydrochloride 80 mg modified release tablet, 28 (*OxyContin*, *Oxycodone Sandoz*)

Highly Specialised Drugs Program (Private Hospital)

Additions

Addition – Item

12998D **RITUXIMAB**, rituximab 100 mg/10 mL injection, 10 mL vial (*Ruxience*)

13000F **RITUXIMAB**, rituximab 100 mg/10 mL injection, 10 mL vial (*Ruxience*)

Addition – Brand

6101D Clozitor, JU – **CLOZAPINE**, clozapine 25 mg tablet, 100

6417R Clozitor, JU – **CLOZAPINE**, clozapine 50 mg tablet, 100

6102E Clozitor, JU – **CLOZAPINE**, clozapine 100 mg tablet, 100

6418T Clozitor, JU – **CLOZAPINE**, clozapine 200 mg tablet, 100

10576P *Ruxience*, PF – **RITUXIMAB**, rituximab 500 mg/50 mL injection, 50 mL vial

11790M *Ruxience*, PF – **RITUXIMAB**, rituximab 500 mg/50 mL injection, 50 mL vial

11804G *Ruxience*, PF – **RITUXIMAB**, rituximab 500 mg/50 mL injection, 50 mL vial

12721M *Ruxience*, PF – **RITUXIMAB**, rituximab 500 mg/50 mL injection, 50 mL vial

9611W *Ruxience*, PF – **RITUXIMAB**, rituximab 500 mg/50 mL injection, 50 mL vial

Addition – Note

12349Y **ADALIMUMAB**, adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe (*Amgevita*)

12368Y	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (<i>Amgevita, Hadlima, Hyrimoz, Idacio</i>)
12384T	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (<i>Amgevita, Hadlima, Hyrimoz, Idacio</i>)
10583B	RITUXIMAB , rituximab 100 mg/10 mL injection, 2 x 10 mL vials (<i>Riximyo, Truxima</i>)
11810N	RITUXIMAB , rituximab 100 mg/10 mL injection, 2 x 10 mL vials (<i>Riximyo, Truxima</i>)

Deletions

Deletion – Brand

6209T	<i>APO-Mycophenolate, TX</i> – MYCOPHENOLATE , mycophenolate mofetil 500 mg tablet, 50
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Alterations

Alteration – Note

9632Y	CLOZAPINE , clozapine 50 mg/mL oral liquid, 100 mL (<i>Clopine Suspension</i>)
6101D	CLOZAPINE , clozapine 25 mg tablet, 100 (<i>Clopine 25, Clozaril 25, Clozitor</i>)
6417R	CLOZAPINE , clozapine 50 mg tablet, 100 (<i>Clopine 50, Clozitor</i>)
6102E	CLOZAPINE , clozapine 100 mg tablet, 100 (<i>Clopine 100, Clozaril 100, Clozitor</i>)
6418T	CLOZAPINE , clozapine 200 mg tablet, 100 (<i>Clopine 200, Clozitor</i>)

Alteration – Restriction

12864C	ECULIZUMAB , eculizumab 300 mg/30 mL injection, 30 mL vial (<i>Soliris</i>)
12896R	ECULIZUMAB , eculizumab 300 mg/30 mL injection, 30 mL vial (<i>Soliris</i>)
12899X	ECULIZUMAB , eculizumab 300 mg/30 mL injection, 30 mL vial (<i>Soliris</i>)
12938Y	ELEXACAFITOR + TEZACAFITOR + IVACAFITOR (&) IVACAFITOR , elexacaftor 100 mg + tezacaftor 50 mg + ivacaftor 75 mg tablet [56] (&) ivacaftor 150 mg tablet [28], 84 (<i>Trikafta</i>)
12841W	RAVULIZUMAB , ravulizumab 300 mg/3 mL injection, 3 mL vial (<i>Ultomiris</i>)
12895Q	RAVULIZUMAB , ravulizumab 300 mg/3 mL injection, 3 mL vial (<i>Ultomiris</i>)
12897T	RAVULIZUMAB , ravulizumab 1.1 g/11 mL injection, 11 mL vial (<i>Ultomiris</i>)
12901B	RAVULIZUMAB , ravulizumab 1.1 g/11 mL injection, 11 mL vial (<i>Ultomiris</i>)

Advance Notices

1 July 2022

Deletion – Brand

6216E	<i>TACROLIMUS APOTEX, TX</i> – TACROLIMUS , tacrolimus 1 mg capsule, 100
6217F	<i>TACROLIMUS APOTEX, TX</i> – TACROLIMUS , tacrolimus 5 mg capsule, 50
6328C	<i>TACROLIMUS APOTEX, TX</i> – TACROLIMUS , tacrolimus 500 microgram capsule, 100

Highly Specialised Drugs Program (Public Hospital)

Additions

Addition – Item

12997C	RITUXIMAB , rituximab 100 mg/10 mL injection, 10 mL vial (<i>Ruxience</i>)
13001G	RITUXIMAB , rituximab 100 mg/10 mL injection, 10 mL vial (<i>Ruxience</i>)

Addition – Brand

5628F	<i>Clozitor, JU</i> – CLOZAPINE , clozapine 25 mg tablet, 100
5626D	<i>Clozitor, JU</i> – CLOZAPINE , clozapine 50 mg tablet, 100
5629G	<i>Clozitor, JU</i> – CLOZAPINE , clozapine 100 mg tablet, 100
5627E	<i>Clozitor, JU</i> – CLOZAPINE , clozapine 200 mg tablet, 100
10593M	<i>Ruxience, PF</i> – RITUXIMAB , rituximab 500 mg/50 mL injection, 50 mL vial
11800C	<i>Ruxience, PF</i> – RITUXIMAB , rituximab 500 mg/50 mL injection, 50 mL vial
11805H	<i>Ruxience, PF</i> – RITUXIMAB , rituximab 500 mg/50 mL injection, 50 mL vial
12739L	<i>Ruxience, PF</i> – RITUXIMAB , rituximab 500 mg/50 mL injection, 50 mL vial
9544H	<i>Ruxience, PF</i> – RITUXIMAB , rituximab 500 mg/50 mL injection, 50 mL vial

Addition – Note

- 12417M **ADALIMUMAB**, adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe (*Amgevita*)
- 12348X **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (*Amgevita, Hadlima, Hyrimoz, Idacio*)
- 12355G **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (*Amgevita, Hadlima, Hyrimoz, Idacio*)
- 10591K **RITUXIMAB**, rituximab 100 mg/10 mL injection, 2 x 10 mL vials (*Riximyo, Truxima*)
- 11813R **RITUXIMAB**, rituximab 100 mg/10 mL injection, 2 x 10 mL vials (*Riximyo, Truxima*)

Deletions**Deletion – Brand**

- 9502D *APO-Mycophenolate, TX* – **MYCOPHENOLATE**, mycophenolate mofetil 500 mg tablet, 50

Alterations**Alteration – Note**

- 5630H **CLOZAPINE**, clozapine 50 mg/mL oral liquid, 100 mL (*Clopine Suspension*)
- 5628F **CLOZAPINE**, clozapine 25 mg tablet, 100 (*Clopine 25, Clozaril 25, Clozitor*)
- 5626D **CLOZAPINE**, clozapine 50 mg tablet, 100 (*Clopine 50, Clozitor*)
- 5629G **CLOZAPINE**, clozapine 100 mg tablet, 100 (*Clopine 100, Clozaril 100, Clozitor*)
- 5627E **CLOZAPINE**, clozapine 200 mg tablet, 100 (*Clopine 200, Clozitor*)

Alteration – Restriction

- 12840T **ECULIZUMAB**, eculizumab 300 mg/30 mL injection, 30 mL vial (*Soliris*)
- 12877R **ECULIZUMAB**, eculizumab 300 mg/30 mL injection, 30 mL vial (*Soliris*)
- 12900Y **ECULIZUMAB**, eculizumab 300 mg/30 mL injection, 30 mL vial (*Soliris*)
- 12936W **ELEXACAFITOR + TEZACAFITOR + IVACAFITOR (&) IVACAFITOR**, elexacafitor 100 mg + tezacafitor 50 mg + ivacafitor 75 mg tablet [56] (&) ivacafitor 150 mg tablet [28], 84 (*Trikafta*)
- 12884D **RAVULIZUMAB**, ravulizumab 300 mg/3 mL injection, 3 mL vial (*Ultomiris*)
- 12898W **RAVULIZUMAB**, ravulizumab 300 mg/3 mL injection, 3 mL vial (*Ultomiris*)
- 12856P **RAVULIZUMAB**, ravulizumab 1.1 g/11 mL injection, 11 mL vial (*Ultomiris*)
- 12883C **RAVULIZUMAB**, ravulizumab 1.1 g/11 mL injection, 11 mL vial (*Ultomiris*)

Advance Notices

1 July 2022

Deletion – Brand

- 9558C *TACROLIMUS APOTEX, TX* – **TACROLIMUS**, tacrolimus 500 microgram capsule, 100
- 9560E *TACROLIMUS APOTEX, TX* – **TACROLIMUS**, tacrolimus 1 mg capsule, 100
- 9561F *TACROLIMUS APOTEX, TX* – **TACROLIMUS**, tacrolimus 5 mg capsule, 50

Highly Specialised Drugs Program (Community Access)**Additions****Addition – Brand**

- 10289M *Clozitor, JU* – **CLOZAPINE**, clozapine 25 mg tablet, 100
- 10302F *Clozitor, JU* – **CLOZAPINE**, clozapine 50 mg tablet, 100
- 10358E *Clozitor, JU* – **CLOZAPINE**, clozapine 100 mg tablet, 100
- 10288L *Clozitor, JU* – **CLOZAPINE**, clozapine 200 mg tablet, 100

Alterations**Alteration – Note**

- 10341G **CLOZAPINE**, clozapine 50 mg/mL oral liquid, 100 mL (*Clopine Suspension*)
- 10289M **CLOZAPINE**, clozapine 25 mg tablet, 100 (*Clopine 25, Clozaril 25, Clozitor*)
- 10302F **CLOZAPINE**, clozapine 50 mg tablet, 100 (*Clopine 50, Clozitor*)
- 10358E **CLOZAPINE**, clozapine 100 mg tablet, 100 (*Clopine 100, Clozaril 100, Clozitor*)

10288L **CLOZAPINE**, clozapine 200 mg tablet, 100 (*Clopine 200, Clozitor*)

Repatriation Pharmaceutical Benefits

Deletions

Deletion – Item

4089F **IPRATROPIUM**, ipratropium bromide monohydrate 22 microgram/actuation nasal spray, 180 actuations (*Atrovent Nasal Aqueous*)

4090G **IPRATROPIUM**, ipratropium bromide monohydrate 44 microgram/actuation nasal spray, 180 actuations (*Atrovent Nasal Forte*)

Deletion – Brand

10169F *Clopidogrel APOTEX, GX* – **CLOPIDOGREL**, clopidogrel 75 mg tablet, 28

Advance Notices

1 July 2022

Deletion – Brand

4444X *Risedro once a week, RW* – **RISEDRONATE**, risedronate sodium 35 mg tablet, 4

General Pharmaceutical Benefits

■ ESOMEPRAZOLE

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note The treatment must not be prescribed under this restriction for any of the following PBS-indications: (i) gastro-oesophageal reflux disease (where the word 'complex' is absent), (ii) scleroderma oesophagus, (iii) pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion, (iv) peptic ulcer, (v) eradication of **Helicobacter pylori**.

Note A standard dose proton pump inhibitor is one of: esomeprazole 20 mg, lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, rabeprazole 20 mg.

Note A high dose proton pump inhibitor is: esomeprazole 40 mg.

Note Pharmaceutical benefits that have the form esomeprazole tablet 40 mg and pharmaceutical benefits that have the form esomeprazole capsule 40 mg are equivalent for the purposes of substitution.

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

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

Note This authority approval must be sought by the specified specialist prescriber.

Authority required

Complex gastro-oesophageal reflux disease (GORD)

Treatment Phase: One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control

Treatment criteria:

- Must be treated by a gastroenterologist; OR
- Must be treated by a surgeon with expertise in the upper gastrointestinal tract.

Clinical criteria:

- The treatment must be: (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI, **AND**
- Patient must have symptoms inadequately controlled with each of: (i) a high dose proton pump inhibitor (PPI) administered once daily, (ii) a standard dose PPI administered twice daily; treatment is for: (1) establishment of symptom control; OR
- Patient must be assessed for the risks/benefits of a step-down in dosing from a high dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for: (2) maintenance treatment; OR
- Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for: (3) re-establishment of symptom control; OR
- Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: (2) maintenance treatment, but with the quantity sought in this authority application being up to 1 pack per dispensing.

Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction.

esomeprazole 40 mg enteric capsule, 30

12290W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*33.52	34.82	^a Noxicid Caps [AL]

esomeprazole 40 mg enteric tablet, 30

12283L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*33.52	34.82	^a APO-Esomeprazole [TY] ^a Esomeprazole GH [GQ] ^a Esomeprazole Mylan [AL] ^a Esomeprazole Sandoz [SZ] ^a Esopreze [BG] ^a Nexole [RF]	^a Esomeprazole Apotex [TX] ^a Esomeprazole GxP [AF] ^a Esomeprazole RBX [RA] ^a Esomeprazole SZ [HX] ^a Nexazole [RW] ^a NOUMED ESOMEPRAZOLE [VO]
			^B 10.00	*43.52	34.82	^a Nexium [AP]	

■ OLAPARIB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) apalutamide, (iii) darolutamide, (iv) enzalutamide.

Note Special Pricing Arrangements apply.

Authority required

Castration resistant metastatic carcinoma of the prostate

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must not be subsidised in combination with: (i) chemotherapy, (ii) a novel hormonal drug.

olaparib 100 mg tablet, 56

12921C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*6630.72	42.50	Lynparza [AP]

olaparib 150 mg tablet, 56

12913P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*6630.72	42.50	Lynparza [AP]

■ OLAPARIB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) apalutamide, (iii) darolutamide, (iv) enzalutamide.

Note Special Pricing Arrangements apply.

Authority required

Castration resistant metastatic carcinoma of the prostate

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation, **AND**
- The treatment must not be subsidised in combination with: (i) chemotherapy, (ii) a novel hormonal drug, **AND**
- The condition must have progressed following prior treatment that included a novel hormonal drug for this condition (metastatic/non-metastatic disease), **AND**
- Patient must have a WHO performance status of 2 or less.

Treatment criteria:

- Patient must be undergoing treatment with this drug for the first time.

Authority required

Castration resistant metastatic carcinoma of the prostate

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements

Clinical criteria:

- Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 April 2022, **AND**
- The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation, **AND**
- The treatment must not be subsidised in combination with: (i) chemotherapy, (ii) a novel hormonal drug, **AND**
- The condition must have progressed following prior treatment that included a novel hormonal drug for this condition (metastatic/non-metastatic disease), prior to initiating non-PBS-subsidised treatment with this drug, **AND**
- Patient must have had a WHO performance status of 2 or less prior to initiating non-PBS-subsidised treatment.

Treatment criteria:

- Patient must be undergoing continuing treatment with this drug where non-PBS-subsidised treatment was for untreated (with this drug) disease which also has not progressed on non-PBS-subsidised treatment.

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

olaparib 100 mg tablet, 56

12932P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*6630.72	42.50	Lynparza [AP]

olaparib 150 mg tablet, 56

12929L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*6630.72	42.50	Lynparza [AP]

■ OXYCODONE

Caution The risk of drug dependence is high.

Note This treatment is not suitable for 'as-required' pain relief.

Note OxyContin modified release tablets are intended to be crush-deterrent and to reduce the rapid release of oxycodone upon accidental or intentional misuse.

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 Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

Authority required (STREAMLINED)

10755

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

Clinical criteria:

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority required (STREAMLINED)

10748

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

Clinical criteria:

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority required (STREAMLINED)

10752

Chronic severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

- (i) is less than 12 months; or
- (ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or
- (iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
- (iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

oxycodone hydrochloride 10 mg modified release tablet, 28

8385H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	27.90	29.20	^a Oxycodone Sandoz [SZ]	^a OxyContin [MF]

oxycodone hydrochloride 20 mg modified release tablet, 28

8386J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	36.38	37.68	^a Oxycodone Sandoz [SZ]	^a OxyContin [MF]

oxycodone hydrochloride 40 mg modified release tablet, 28

8387K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	51.11	42.50	^a Oxycodone Sandoz [SZ]	^a OxyContin [MF]

oxycodone hydrochloride 80 mg modified release tablet, 28

8388L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	72.95	42.50	^a Oxycodone Sandoz [SZ]	^a OxyContin [MF]

■ SECUKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of secukinumab, certolizumab pegol and golimumab for adult patients with non-radiographic axial spondyloarthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to secukinumab, certolizumab pegol and golimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment 3 times (once with any biological medicine) within the same treatment cycle, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

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

How to prescribe PBS-subsidised biological medicine treatment with secukinumab, certolizumab pegol and golimumab

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient)
 - (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
 - (iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years); or
 - (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).
- A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of

therapy.

(2) Continuing treatment.

For continuing courses of PBS-subsidised biological medicine it is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

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

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

(4) Baseline measurements to determine response.

A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records. For a new patient, the BASDAI score used to determine baseline disease severity must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.

Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

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

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must qualify under the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

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

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial 1 (New patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patients) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 20 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 20 weeks treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

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

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

secukinumab 150 mg/mL injection, 1 mL pen device

12297F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	709.65	42.50	Cosentyx [NV]

▪ VENETOCLAX

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

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

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Pharmaceutical benefits that have the forms venetoclax 10 mg tablet, 14 and venetoclax 10 mg tablet, 2 are equivalent for the purposes of substitution.

Authority required

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Dose modification

Clinical criteria:

- The treatment must be for dose titration purposes.

venetoclax 10 mg tablet, 2

12999E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	7	..	..	*107.74	42.50	^a Venclexta [VE]

venetoclax 10 mg tablet, 14

11624T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	107.74	42.50	^a Venclexta [VE]

Palliative Care

■ OXYCODONE

Caution The risk of drug dependence is high.

Note This treatment is not suitable for 'as-required' pain relief.

Note OxyContin modified release tablets are intended to be crush-deterrent and to reduce the rapid release of oxycodone upon accidental or intentional misuse.

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 Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

Authority required

Severe disabling pain

Clinical criteria:

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Treatment criteria:

- Patient must be undergoing palliative care.

Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

oxycodone hydrochloride 10 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
12518W	2	..	..	*38.90	40.20	^a Oxycodone Sandoz [SZ]	^a OxyContin [MF]

NP

oxycodone hydrochloride 20 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
12510K	2	..	..	*55.86	42.50	^a Oxycodone Sandoz [SZ]	^a OxyContin [MF]

NP

oxycodone hydrochloride 40 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
12525F	2	..	..	*85.32	42.50	^a Oxycodone Sandoz [SZ]	^a OxyContin [MF]

NP

oxycodone hydrochloride 80 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
12527H	2	..	..	*129.60	42.50	^a Oxycodone Sandoz [SZ]	^a OxyContin [MF]

NP

Highly Specialised Drugs Program (Private Hospital)

■ ADALIMUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle under the Initial 3 treatment restriction.

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

How to prescribe PBS-subsidised biological medicine treatment therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 12 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 12 months with the same medicine (initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 12 months).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 12 months (initial 3 - Recommencement of treatment after a break in biological medicine of more than 12 months) Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

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

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

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

To avoid confusion, an application for a patient who wishes to swap to an alternate biological medicine should be accompanied by the approved authority prescription or remaining repeats for the biological medicine the patient is ceasing.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12 months break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 12 months, must qualify under the initial 3 restriction and meet the relevant criteria and index of disease severity.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be submitted to Services Australia if subsequent authority applications are required.

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

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

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required (STREAMLINED)

12116

Severe active juvenile idiopathic arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

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

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

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

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

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe

12349Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*859.06	Amgevita [TX]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12368Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	859.06	^a Amgevita [TX] ^a Hyrimoz [SZ]	^a Hadlima [RF] ^a Idacio [PK]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

12384T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	859.06	^a Amgevita [TX] ^a Hyrimoz [SZ]	^a Hadlima [RF] ^a Idacio [PK]

■ CLOZAPINE

Note Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed: Novartis Clozaril Patient Monitoring System (eCPMS), Pfizer ClopineCentral or Juno Connected Clozitor.

Authority required (STREAMLINED)

9490

Schizophrenia

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a psychiatrist or in consultation with the psychiatrist affiliated with the hospital or specialised unit managing the patient.

Clinical criteria:

- Patient must be non-responsive to other neuroleptic agents; OR
- Patient must be intolerant of other neuroleptic agents.

Patients must complete at least 18 weeks of initial treatment under this restriction before being able to qualify for treatment under the continuing restriction.

The name of the consulting psychiatrist should be included in the patient's medical records.

A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

clozapine 50 mg/mL oral liquid, 100 mL

9632Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	148.18	Clopine Suspension [PF]

clozapine 100 mg tablet, 100

6102E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*259.86	Clopine 100 [PF] Clozitor [JU]	Clozaril 100 [GO]

clozapine 200 mg tablet, 100

6418T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*511.94	Clopine 200 [PF]	Clozitor [JU]

clozapine 25 mg tablet, 100

6101D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*76.42	Clopine 25 [PF] Clozitor [JU]	Clozaril 25 [GO]

clozapine 50 mg tablet, 100

6417R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*142.24	Clopine 50 [PF]	Clozitor [JU]

■ ECULIZUMAB

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

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

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

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Special Pricing Arrangements apply.

Authority required

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Initial treatment - Initial 1 (new patient) induction doses

Clinical criteria:

- Patient must not have received prior treatment with this drug for this condition, **AND**
- Patient must have a diagnosis of PNH established by flow cytometry, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10%, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy; OR
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms; OR
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded; OR
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m², where causes other than PNH have been excluded; OR
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded, **AND**
- The treatment must not be in combination with ravulizumab.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

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

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

- (i) Haemoglobin (g/L)
- (ii) Platelets (x10⁹/L)
- (iii) White Cell Count (x10⁹/L)
- (iv) Reticulocytes (x10⁹/L)
- (v) Neutrophils (x10⁹/L)
- (vi) Granulocyte clone size (%)
- (vii) Lactate Dehydrogenase (LDH) and the upper limit of normal (ULN) for the reporting laboratory
- (viii) Multiple of LDH , ULN

eculizumab 300 mg/30 mL injection, 30 mL vial

12896R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	..	..	*45172.82	Soliris [XI]

■ ECULIZUMAB

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

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

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Balance of Supply' patient must qualify under the 'First Continuing Treatment' criteria.

Note This Balance of Supply restriction will cease to operate from 5 years after the date specified in the clinical criteria.

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

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

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Note Special Pricing Arrangements apply.

Authority required

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Balance of Supply (transition from non-PBS-subsidised treatment during induction phase)

Clinical criteria:

- Patient must have received non-PBS-subsidised eculizumab for this condition prior to 1 March 2022, **AND**
- Patient must have received insufficient quantity to complete the induction treatment phase, **AND**
- Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with eculizumab, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with eculizumab, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with eculizumab, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with eculizumab; OR
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with eculizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with eculizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with eculizumab; OR
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m², where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with eculizumab, **AND**
- The treatment must not be in combination with ravulizumab.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

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

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials to complete the induction treatment phase, as per the Product Information.

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

- (i) Haemoglobin (g/L)
- (ii) Platelets (x10⁹/L)
- (iii) White Cell Count (x10⁹/L)
- (iv) Reticulocytes (x10⁹/L)
- (v) Neutrophils (x10⁹/L)
- (vi) Granulocyte clone size (%)
- (vii) Lactate Dehydrogenase (LDH) and the upper limit of normal (ULN) for the reporting laboratory
- (viii) Multiple of LDH , ULN

eculizumab 300 mg/30 mL injection, 30 mL vial

12864C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5688.41	Soliris [XI]

▪ **ECULIZUMAB**

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

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

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

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Special Pricing Arrangements apply.

Authority required

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Initial treatment - Initial 2 (switching from PBS-subsidised ravulizumab for pregnancy)

Clinical criteria:

- Patient must be planning pregnancy; OR
- Patient must be pregnant, **AND**
- Patient must have received PBS-subsidised treatment with ravulizumab for this condition, **AND**
- The treatment must not be in combination with ravulizumab.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

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

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Patient may qualify under this treatment phase more than once. In the event of miscarriage, patient may continue on eculizumab if patient is stable, and/or is planning a subsequent pregnancy. For continuing PBS-subsidised treatment, a 'Switching' patient must proceed under the 'Subsequent Continuing Treatment' criteria.

Authority required

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Grandfather 1 (transition from non-PBS-subsidised treatment) - maintenance phase

Clinical criteria:

- Patient must have received non-PBS-subsidised eculizumab for this condition prior to 1 March 2022, **AND**
- Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with eculizumab, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with eculizumab, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with eculizumab, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with eculizumab; OR
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with eculizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with eculizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with eculizumab; OR
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m², where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with eculizumab, **AND**
- The treatment must not be in combination with ravulizumab.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

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

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

(i) Haemoglobin (g/L)

- (ii) Platelets ($\times 10^9/L$)
- (iii) White Cell Count ($\times 10^9/L$)
- (iv) Reticulocytes ($\times 10^9/L$)
- (v) Neutrophils ($\times 10^9/L$)
- (vi) Granulocyte clone size (%)
- (vii) Lactate Dehydrogenase (LDH) and the upper limit of normal (ULN) for the reporting laboratory
- (viii) Multiple of LDH , ULN

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'First Continuing Treatment' criteria.

Note This grandfather restriction will cease to operate from 5 years after the date specified in the clinical criteria.

Authority required

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Grandfather 2 (transition from LSDP-funded eculizumab)

Clinical criteria:

- Patient must have previously received eculizumab for the treatment of this condition funded under the Australian Government's Life Saving Drugs Program (LSDP), **AND**
- Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with eculizumab, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with eculizumab, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with eculizumab, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with eculizumab; OR
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with eculizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with eculizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with eculizumab; OR
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m², where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with eculizumab, **AND**
- The treatment must not be in combination with ravulizumab.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

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

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

- (i) Haemoglobin (g/L)
- (ii) Platelets ($\times 10^9/L$)
- (iii) White Cell Count ($\times 10^9/L$)
- (iv) Reticulocytes ($\times 10^9/L$)
- (v) Neutrophils ($\times 10^9/L$)
- (vi) Granulocyte clone size (%)
- (vii) Lactate Dehydrogenase (LDH) and the upper limit of normal (ULN) for the reporting laboratory
- (viii) Multiple of LDH , ULN

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'First Continuing Treatment' criteria.

Authority required

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: First Continuing Treatment

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug for this condition under an 'Initial', 'Balance of Supply', or 'Grandfather' treatment criteria, **AND**

- The treatment must not be in combination with ravulizumab.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

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

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

- (i) Haemoglobin (g/L)
- (ii) Platelets ($\times 10^9/L$)
- (iii) White Cell Count ($\times 10^9/L$)
- (iv) Reticulocytes ($\times 10^9/L$)
- (v) Neutrophils ($\times 10^9/L$)
- (vi) Granulocyte clone size (%)
- (vii) Lactate Dehydrogenase (LDH) and the upper limit of normal (ULN) for the reporting laboratory
- (viii) Multiple of LDH , ULN

Authority required

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Subsequent Continuing Treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the 'First Continuing Treatment' or 'Switch' criteria, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, **AND**
- The treatment must not be in combination with ravulizumab.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

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

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

eculizumab 300 mg/30 mL injection, 30 mL vial

12899X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	5	..	*33891.58	Soliris [XI]

▪ **ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**

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

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

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

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

Note For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor and elexacaftor/ tezacaftor/ ivacaftor.

Note Special Pricing Arrangements apply.

Authority required

Cystic fibrosis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have at least one F508del mutation in the cystic fibrosis transmembrane conductance (CFTR) gene, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**

- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, prior to initiating treatment with this drug.

Population criteria:

- Patient must be 12 years of age or older.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

- (1) a completed authority prescription; and
- (2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and
- (3) details of the pathology report substantiating the patient having at least one F508del mutation - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and
- (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

Authority required

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be 12 years of age or older.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

- (1) a completed authority prescription; and
- (2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and
- (3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

elhexacaftor 100 mg + tezacaftor 50 mg + ivacaftor 75 mg tablet [56] (&) ivacaftor 150 mg tablet [28], 84

12938Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	21422.78	Trikafta [VR]

▪ **RAVULIZUMAB**

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

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

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

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

Note Special Pricing Arrangements apply.

Authority required

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Initial treatment - Initial 1 (new patient) induction dose

Clinical criteria:

- Patient must not have received prior treatment with this drug for this condition, **AND**
- Patient must have a diagnosis of PNH established by flow cytometry, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10%, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy; OR
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms; OR

- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded; OR
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m², where causes other than PNH have been excluded; OR
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded, **AND**
- The treatment must not be in combination with eculizumab.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

Population criteria:

- Patient must be aged 18 years or over.

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

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials for a single loading dose based on the patient's weight, as per the Product Information

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

- (i) Haemoglobin (g/L)
- (ii) Platelets (x10⁹/L)
- (iii) White Cell Count (x10⁹/L)
- (iv) Reticulocytes (x10⁹/L)
- (v) Neutrophils (x10⁹/L)
- (vi) Granulocyte clone size (%)
- (vii) Lactate Dehydrogenase (LDH) and the upper limit of normal (ULN) for the reporting laboratory
- (viii) Multiple of LDH , ULN

Authority required

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Initial treatment - Initial 2 (switch from LSDP eculizumab) induction dose

Clinical criteria:

- Patient must have previously received eculizumab for the treatment of this condition funded under the Australian Government's Life Saving Drugs Program (LSDP), **AND**
- Patient must have a diagnosis of PNH established by flow cytometry prior to LSDP-funded treatment with eculizumab, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to LSDP-funded treatment with eculizumab, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to LSDP-funded treatment with eculizumab, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to LSDP-funded treatment with eculizumab; OR
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to LSDP-funded treatment with eculizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to LSDP-funded treatment with eculizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to LSDP-funded treatment with eculizumab; OR
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to LSDP-funded treatment with eculizumab; OR
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m², where causes other than PNH have been excluded prior to LSDP-funded treatment with eculizumab; OR
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to LSDP-funded treatment with eculizumab, **AND**
- The treatment must not be in combination with eculizumab.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

Population criteria:

- Patient must be aged 18 years or over.

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

- (1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials for a single loading dose based on the patient's weight, as per the Product Information

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

- (i) Haemoglobin (g/L)
- (ii) Platelets ($\times 10^9/L$)
- (iii) White Cell Count ($\times 10^9/L$)
- (iv) Reticulocytes ($\times 10^9/L$)
- (v) Neutrophils ($\times 10^9/L$)
- (vi) Granulocyte clone size (%)
- (vii) Lactate Dehydrogenase (LDH) and the upper limit of normal (ULN) for the reporting laboratory
- (viii) Multiple of LDH, ULN

Authority required

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Return from PBS-subsidised eculizumab - induction dose

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have received prior PBS-subsidised treatment with eculizumab through the 'Initial treatment - Initial 2 (switching from PBS-subsidised ravulizumab for pregnancy)' criteria, **AND**
- The treatment must not be in combination with eculizumab.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

Population criteria:

- Patient must be aged 18 years or over.

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

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials for a single loading dose based on the patient's weight, as per the Product Information

Patient may qualify under this treatment phase more than once for the purposes of family planning. Where long-term continuing PBS-subsidised treatment with this drug is planned, a 'Returning' patient may proceed under the 'Subsequent Continuing Treatment' criteria.

ravulizumab 1.1 g/11 mL injection, 11 mL vial

12901B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	25265.54	Ultomiris [XI]

ravulizumab 300 mg/3 mL injection, 3 mL vial

12841W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	6925.35	Ultomiris [XI]

▪ **RAVULIZUMAB**

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

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

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

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

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

Note Special Pricing Arrangements apply.

Authority required

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Grandfather (transition from non-PBS-subsidised treatment)

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 March 2022, **AND**

- Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with ravulizumab, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with ravulizumab, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with ravulizumab, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, the details of which must be kept with the patient's record, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with ravulizumab; OR
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with ravulizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with ravulizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with ravulizumab; OR
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with ravulizumab; OR
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m², where causes other than PNH have been excluded prior to commencing treatment with ravulizumab; OR
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with ravulizumab, **AND**
- The treatment must not be in combination with eculizumab.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

Population criteria:

- Patient must be aged 18 years or over.

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

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested.

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

- (i) Haemoglobin (g/L)
- (ii) Platelets (x10⁹/L)
- (iii) White Cell Count (x10⁹/L)
- (iv) Reticulocytes (x10⁹/L)
- (v) Neutrophils (x10⁹/L)
- (vi) Granulocyte clone size (%)
- (vii) Lactate Dehydrogenase (LDH) and the upper limit of normal (ULN) for the reporting laboratory
- (viii) Multiple of LDH, ULN

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'First Continuing Treatment' criteria.

Note This grandfather restriction will cease to operate from 5 years after the date specified in the clinical criteria.

Authority required

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: First Continuing Treatment

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug for this condition under an 'Initial' or 'Grandfather' treatment criteria, **AND**
- The treatment must not be in combination with eculizumab.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

Population criteria:

- Patient must be aged 18 years or over.

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

- (1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested.

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

- (i) Haemoglobin (g/L)
- (ii) Platelets ($\times 10^9/L$)
- (iii) White Cell Count ($\times 10^9/L$)
- (iv) Reticulocytes ($\times 10^9/L$)
- (v) Neutrophils ($\times 10^9/L$)
- (vi) Granulocyte clone size (%)
- (vii) Lactate Dehydrogenase (LDH) and the upper limit of normal (ULN) for the reporting laboratory
- (viii) Multiple of LDH , ULN

Authority required

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Subsequent Continuing Treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the 'First Continuing Treatment' or 'Return' criteria, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, **AND**
- The treatment must not be in combination with eculizumab.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

Population criteria:

- Patient must be aged 18 years or over.

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

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested.

ravulizumab 1.1 g/11 mL injection, 11 mL vial

12897T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	25265.54	Ultomiris [XI]

ravulizumab 300 mg/3 mL injection, 3 mL vial

12895Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	6925.35	Ultomiris [XI]

▪ **RITUXIMAB**

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

Note Pharmaceutical benefits that have the form rituximab 100 mg/10 mL injection, 2 x 10 mL vials and pharmaceutical benefits that have the form rituximab 100 mg/10 mL injection, 10 mL vial are equivalent for the purposes of substitution.

Note Risk of end-organ damage or mortality includes a minimum of one of the following: Glomerulonephritis with risk of progression

- Risk to sight including scleritis/episcleritis, sudden visual loss, uveitis, retinal changes (vasculitis/thrombosis/exudates/haemorrhage)
- Bronchial/subglottic obstruction
- Pulmonary haemorrhage
- Parenchymal lung disease
- Sensory neural hearing loss
- Recurrent sinonasal disease requiring recurrent surgical interventions
- Meningitis, organic confusion, seizures, stroke, cord lesion, cranial nerve palsy, sensory peripheral neuropathy, motor mononeuritis multiplex

Note Patients could be considered contraindicated, refractory, or unable to tolerate cyclophosphamide for one of the following reasons: Cyclophosphamide is contraindicated as per the TGA approved Product Information;

- Cyclophosphamide is not recommended due to the need to preserve gonad function;
- Patient experiences severe toxicity to cyclophosphamide that warrants cessation of treatment;
- Patient has life- or organ-threatening deterioration at any time during treatment with cyclophosphamide, where the deterioration is thought to be due to severe uncontrolled active vasculitis;

- Commencing a further treatment cycle with cyclophosphamide would exceed the maximum cumulative dose of cyclophosphamide of 25g; or
- Patient's condition with this indication is persistent despite at least 3 months therapy with cyclophosphamide.

Authority required (STREAMLINED)

9640

Severe active granulomatosis with polyangiitis (Wegeners granulomatosis)

Treatment Phase: Re-induction of remission

Clinical criteria:

- The treatment must be for the re-induction of remission, **AND**
- Patient must have previously received and responded to this drug for this condition, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance of remission

Authority required (STREAMLINED)

9641

Severe active microscopic polyangiitis

Treatment Phase: Re-induction of remission

Clinical criteria:

- The treatment must be for the re-induction of remission, **AND**
- Patient must have previously received and responded to this drug for this condition, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance therapy.

rituximab 100 mg/10 mL injection, 10 mL vial

13000F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	..	..	*431.86	^a Ruxience [PF]

rituximab 100 mg/10 mL injection, 2 x 10 mL vials

11810N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*431.86	^a Riximyo [SZ]	^a Truxima [EW]

▪ RITUXIMAB

Note Pharmaceutical benefits that have the form rituximab 100 mg/10 mL injection, 2 x 10 mL vials and pharmaceutical benefits that have the form rituximab 100 mg/10 mL injection, 10 mL vial are equivalent for the purposes of substitution.

Note Risk of end-organ damage or mortality includes a minimum of one of the following: Glomerulonephritis with risk of progression

- Risk to sight including scleritis/episcleritis, sudden visual loss, uveitis, retinal changes (vasculitis/thrombosis/exudates/haemorrhage)
- Bronchial/subglottic obstruction
- Pulmonary haemorrhage
- Parenchymal lung disease
- Sensory neural hearing loss
- Recurrent sinonasal disease requiring recurrent surgical interventions
- Meningitis, organic confusion, seizures, stroke, cord lesion, cranial nerve palsy, sensory peripheral neuropathy, motor mononeuritis multiplex

Note Patients could be considered contraindicated, refractory, or unable to tolerate cyclophosphamide for one of the following reasons: Cyclophosphamide is contraindicated as per the TGA approved Product Information;

- Cyclophosphamide is not recommended due to the need to preserve gonad function;
- Patient experiences severe toxicity to cyclophosphamide that warrants cessation of treatment;
- Patient has life- or organ-threatening deterioration at any time during treatment with cyclophosphamide, where the deterioration is thought to be due to severe uncontrolled active vasculitis;
- Commencing a further treatment cycle with cyclophosphamide would exceed the maximum cumulative dose of cyclophosphamide of 25g; or
- Patient's condition with this indication is persistent despite at least 3 months therapy with cyclophosphamide.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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.

Authority required

Severe active granulomatosis with polyangiitis (Wegeners granulomatosis)

Treatment Phase: Induction of remission

Clinical criteria:

- The treatment must be for the induction of remission, **AND**
- Patient must not have previously received this drug for this condition, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance of remission

The authority application must be made in writing

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand, Riximyo or Truxima, is encouraged for treatment naive patients.

Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Authority required

Severe active microscopic polyangiitis

Treatment Phase: Induction of remission

Clinical criteria:

- The treatment must be for the induction of remission, **AND**
- Patient must not have previously received this drug for this condition, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance therapy.

The authority application must be made in writing

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand, Riximyo or Truxima, is encouraged for treatment naive patients.

Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Authority required

Severe active granulomatosis with polyangiitis (Wegeners granulomatosis)

Treatment Phase: Re-induction of remission

Clinical criteria:

- The treatment must be for the re-induction of remission, **AND**
- Patient must have previously received and responded to this drug for this condition, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance of remission

The authority application must be made in writing

Authority required

Severe active microscopic polyangiitis

Treatment Phase: Re-induction of remission

Clinical criteria:

- The treatment must be for the re-induction of remission, **AND**
- Patient must have previously received and responded to this drug for this condition, **AND**

- The treatment must in combination with glucocorticoids, **AND**
 - Patient must be at risk of end-organ damage or mortality, **AND**
 - Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.
- Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.
- This drug is not PBS-subsidised for maintenance therapy.
- The authority application must be made in writing

rituximab 100 mg/10 mL injection, 10 mL vial

12998D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	..	..	*149.14	^a Ruxience [PF]

rituximab 100 mg/10 mL injection, 2 x 10 mL vials

10583B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	149.14	^a Riximyo [SZ]	^a Truxima [EW]

Highly Specialised Drugs Program (Public Hospital)

■ ADALIMUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle under the Initial 3 treatment restriction.

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

How to prescribe PBS-subsidised biological medicine treatment therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 12 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 12 months with the same medicine (initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 12 months).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 12 months (initial 3 - Recommencement of treatment after a break in biological medicine of more than 12 months) Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

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

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

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

To avoid confusion, an application for a patient who wishes to swap to an alternate biological medicine should be accompanied by the approved authority prescription or remaining repeats for the biological medicine the patient is ceasing.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12 months break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 12 months, must qualify under the initial 3 restriction and meet the relevant criteria and index of disease severity.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be submitted to Services Australia if subsequent authority applications are required.

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

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

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required (STREAMLINED)

11526

Severe active juvenile idiopathic arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

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

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

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

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

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe

12417M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*818.54	Amgevita [TX]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12355G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	818.54	^a Amgevita [TX] ^a Hyrimoz [SZ]	^a Hadlima [RF] ^a Idacio [PK]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

12348X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	818.54	^a Amgevita [TX] ^a Hyrimoz [SZ]	^a Hadlima [RF] ^a Idacio [PK]

■ CLOZAPINE

Note Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed: Novartis Clozaril Patient Monitoring System (eCPMS), Pfizer ClopineCentral or Juno Connected Clozitor.

Authority required (STREAMLINED)

5015

Schizophrenia

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a psychiatrist or in consultation with the psychiatrist affiliated with the hospital or specialised unit managing the patient.

Clinical criteria:

- Patient must be non-responsive to other neuroleptic agents; OR
- Patient must be intolerant of other neuroleptic agents.

Patients must complete at least 18 weeks of initial treatment under this restriction before being able to qualify for treatment under the continuing restriction.

The name of the consulting psychiatrist should be included in the patient's medical records.

A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

clozapine 50 mg/mL oral liquid, 100 mL

5630H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	135.00	Clopine Suspension [PF]

clozapine 100 mg tablet, 100

5629G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*242.38	Clopine 100 [PF] Clozitor [JU]	Clozaril 100 [GO]

clozapine 200 mg tablet, 100

5627E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*484.76	Clopine 200 [PF]	Clozitor [JU]

clozapine 25 mg tablet, 100

5628F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*64.64	Clopine 25 [PF] Clozitor [JU]	Clozaril 25 [GO]

clozapine 50 mg tablet, 100

5626D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*129.28	Clopine 50 [PF]	Clozitor [JU]

■ ECULIZUMAB

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

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

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

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Special Pricing Arrangements apply.

Authority required

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Initial treatment - Initial 1 (new patient) induction doses

Clinical criteria:

- Patient must not have received prior treatment with this drug for this condition, **AND**
- Patient must have a diagnosis of PNH established by flow cytometry, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10%, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy; OR
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms; OR
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded; OR
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m², where causes other than PNH have been excluded; OR
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded, **AND**
- The treatment must not be in combination with ravulizumab.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

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

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

- (i) Haemoglobin (g/L)
- (ii) Platelets (x10⁹/L)
- (iii) White Cell Count (x10⁹/L)
- (iv) Reticulocytes (x10⁹/L)
- (v) Neutrophils (x10⁹/L)
- (vi) Granulocyte clone size (%)
- (vii) Lactate Dehydrogenase (LDH) and the upper limit of normal (ULN) for the reporting laboratory
- (viii) Multiple of LDH , ULN

eculizumab 300 mg/30 mL injection, 30 mL vial

12840T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	..	..	*45125.04	Soliris [XI]

■ ECULIZUMAB

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

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

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Balance of Supply' patient must qualify under the 'First Continuing Treatment' criteria.

Note This Balance of Supply restriction will cease to operate from 5 years after the date specified in the clinical criteria.

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

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

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Note Special Pricing Arrangements apply.

Authority required

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Balance of Supply (transition from non-PBS-subsidised treatment during induction phase)

Clinical criteria:

- Patient must have received non-PBS-subsidised eculizumab for this condition prior to 1 March 2022, **AND**
- Patient must have received insufficient quantity to complete the induction treatment phase, **AND**
- Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with eculizumab, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with eculizumab, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with eculizumab, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with eculizumab; OR
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with eculizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with eculizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with eculizumab; OR
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m², where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with eculizumab, **AND**
- The treatment must not be in combination with ravulizumab.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

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

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials to complete the induction treatment phase, as per the Product Information.

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

- (i) Haemoglobin (g/L)
- (ii) Platelets (x10⁹/L)
- (iii) White Cell Count (x10⁹/L)
- (iv) Reticulocytes (x10⁹/L)
- (v) Neutrophils (x10⁹/L)
- (vi) Granulocyte clone size (%)
- (vii) Lactate Dehydrogenase (LDH) and the upper limit of normal (ULN) for the reporting laboratory
- (viii) Multiple of LDH , ULN

eculizumab 300 mg/30 mL injection, 30 mL vial

12900Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5640.63	Soliris [XI]

▪ **ECULIZUMAB**

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

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

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

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Special Pricing Arrangements apply.

Authority required

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Initial treatment - Initial 2 (switching from PBS-subsidised ravulizumab for pregnancy)

Clinical criteria:

- Patient must be planning pregnancy; OR
- Patient must be pregnant, **AND**
- Patient must have received PBS-subsidised treatment with ravulizumab for this condition, **AND**
- The treatment must not be in combination with ravulizumab.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

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

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Patient may qualify under this treatment phase more than once. In the event of miscarriage, patient may continue on eculizumab if patient is stable, and/or is planning a subsequent pregnancy. For continuing PBS-subsidised treatment, a 'Switching' patient must proceed under the 'Subsequent Continuing Treatment' criteria.

Authority required

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Grandfather 1 (transition from non-PBS-subsidised treatment) - maintenance phase

Clinical criteria:

- Patient must have received non-PBS-subsidised eculizumab for this condition prior to 1 March 2022, **AND**
- Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with eculizumab, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with eculizumab, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with eculizumab, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with eculizumab; OR
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with eculizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with eculizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with eculizumab; OR
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m², where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with eculizumab, **AND**
- The treatment must not be in combination with ravulizumab.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

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

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

(i) Haemoglobin (g/L)

- (ii) Platelets ($\times 10^9/L$)
- (iii) White Cell Count ($\times 10^9/L$)
- (iv) Reticulocytes ($\times 10^9/L$)
- (v) Neutrophils ($\times 10^9/L$)
- (vi) Granulocyte clone size (%)
- (vii) Lactate Dehydrogenase (LDH) and the upper limit of normal (ULN) for the reporting laboratory
- (viii) Multiple of LDH , ULN

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'First Continuing Treatment' criteria.

Note This grandfather restriction will cease to operate from 5 years after the date specified in the clinical criteria.

Authority required

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Grandfather 2 (transition from LSDP-funded eculizumab)

Clinical criteria:

- Patient must have previously received eculizumab for the treatment of this condition funded under the Australian Government's Life Saving Drugs Program (LSDP), **AND**
- Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with eculizumab, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with eculizumab, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with eculizumab, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with eculizumab; OR
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with eculizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with eculizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with eculizumab; OR
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m², where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with eculizumab, **AND**
- The treatment must not be in combination with ravulizumab.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

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

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

- (i) Haemoglobin (g/L)
- (ii) Platelets ($\times 10^9/L$)
- (iii) White Cell Count ($\times 10^9/L$)
- (iv) Reticulocytes ($\times 10^9/L$)
- (v) Neutrophils ($\times 10^9/L$)
- (vi) Granulocyte clone size (%)
- (vii) Lactate Dehydrogenase (LDH) and the upper limit of normal (ULN) for the reporting laboratory
- (viii) Multiple of LDH , ULN

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'First Continuing Treatment' criteria.

Authority required

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: First Continuing Treatment

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug for this condition under an 'Initial', 'Balance of Supply', or 'Grandfather' treatment criteria, **AND**

- The treatment must not be in combination with ravulizumab.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

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

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

- (i) Haemoglobin (g/L)
- (ii) Platelets ($\times 10^9/L$)
- (iii) White Cell Count ($\times 10^9/L$)
- (iv) Reticulocytes ($\times 10^9/L$)
- (v) Neutrophils ($\times 10^9/L$)
- (vi) Granulocyte clone size (%)
- (vii) Lactate Dehydrogenase (LDH) and the upper limit of normal (ULN) for the reporting laboratory
- (viii) Multiple of LDH , ULN

Authority required

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Subsequent Continuing Treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the 'First Continuing Treatment' or 'Switch' criteria, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, **AND**
- The treatment must not be in combination with ravulizumab.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

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

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

eculizumab 300 mg/30 mL injection, 30 mL vial

12877R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	5	..	*33843.78	Soliris [XI]

▪ **ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**

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

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

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

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

Note For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor and elexacaftor/ tezacaftor/ ivacaftor.

Note Special Pricing Arrangements apply.

Authority required

Cystic fibrosis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have at least one F508del mutation in the cystic fibrosis transmembrane conductance (CFTR) gene, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**

- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, prior to initiating treatment with this drug.

Population criteria:

- Patient must be 12 years of age or older.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

- (1) a completed authority prescription; and
- (2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and
- (3) details of the pathology report substantiating the patient having at least one F508del mutation - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and
- (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

Authority required

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be 12 years of age or older.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

- (1) a completed authority prescription; and
- (2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and
- (3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

elxacaftor 100 mg + tezacaftor 50 mg + ivacaftor 75 mg tablet [56] (&) ivacaftor 150 mg tablet [28], 84

12936W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	21375.00	Trikafta [VR]

▪ **RAVULIZUMAB**

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

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

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

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

Note Special Pricing Arrangements apply.

Authority required

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Initial treatment - Initial 1 (new patient) induction dose

Clinical criteria:

- Patient must not have received prior treatment with this drug for this condition, **AND**
- Patient must have a diagnosis of PNH established by flow cytometry, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10%, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy; OR
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms; OR

- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded; OR
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m², where causes other than PNH have been excluded; OR
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded, **AND**
- The treatment must not be in combination with eculizumab.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

Population criteria:

- Patient must be aged 18 years or over.

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

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials for a single loading dose based on the patient's weight, as per the Product Information

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

- (i) Haemoglobin (g/L)
- (ii) Platelets (x10⁹/L)
- (iii) White Cell Count (x10⁹/L)
- (iv) Reticulocytes (x10⁹/L)
- (v) Neutrophils (x10⁹/L)
- (vi) Granulocyte clone size (%)
- (vii) Lactate Dehydrogenase (LDH) and the upper limit of normal (ULN) for the reporting laboratory
- (viii) Multiple of LDH , ULN

Authority required

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Initial treatment - Initial 2 (switch from LSDP eculizumab) induction dose

Clinical criteria:

- Patient must have previously received eculizumab for the treatment of this condition funded under the Australian Government's Life Saving Drugs Program (LSDP), **AND**
- Patient must have a diagnosis of PNH established by flow cytometry prior to LSDP-funded treatment with eculizumab, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to LSDP-funded treatment with eculizumab, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to LSDP-funded treatment with eculizumab, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to LSDP-funded treatment with eculizumab; OR
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to LSDP-funded treatment with eculizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to LSDP-funded treatment with eculizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to LSDP-funded treatment with eculizumab; OR
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to LSDP-funded treatment with eculizumab; OR
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m², where causes other than PNH have been excluded prior to LSDP-funded treatment with eculizumab; OR
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to LSDP-funded treatment with eculizumab, **AND**
- The treatment must not be in combination with eculizumab.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

Population criteria:

- Patient must be aged 18 years or over.

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

- (1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials for a single loading dose based on the patient's weight, as per the Product Information

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

- (i) Haemoglobin (g/L)
- (ii) Platelets ($\times 10^9/L$)
- (iii) White Cell Count ($\times 10^9/L$)
- (iv) Reticulocytes ($\times 10^9/L$)
- (v) Neutrophils ($\times 10^9/L$)
- (vi) Granulocyte clone size (%)
- (vii) Lactate Dehydrogenase (LDH) and the upper limit of normal (ULN) for the reporting laboratory
- (viii) Multiple of LDH, ULN

Authority required

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Return from PBS-subsidised eculizumab - induction dose

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have received prior PBS-subsidised treatment with eculizumab through the 'Initial treatment - Initial 2 (switching from PBS-subsidised ravulizumab for pregnancy)' criteria, **AND**
- The treatment must not be in combination with eculizumab.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

Population criteria:

- Patient must be aged 18 years or over.

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

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials for a single loading dose based on the patient's weight, as per the Product Information

Patient may qualify under this treatment phase more than once for the purposes of family planning. Where long-term continuing PBS-subsidised treatment with this drug is planned, a 'Returning' patient may proceed under the 'Subsequent Continuing Treatment' criteria.

ravulizumab 1.1 g/11 mL injection, 11 mL vial

12856P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	25217.76	Ultomiris [XI]

ravulizumab 300 mg/3 mL injection, 3 mL vial

12898W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	6877.57	Ultomiris [XI]

▪ **RAVULIZUMAB**

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

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

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

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

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

Note Special Pricing Arrangements apply.

Authority required

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Grandfather (transition from non-PBS-subsidised treatment)

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 March 2022, **AND**

- Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with ravulizumab, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with ravulizumab, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with ravulizumab, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, the details of which must be kept with the patient's record, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with ravulizumab; OR
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with ravulizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with ravulizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with ravulizumab; OR
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with ravulizumab; OR
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m², where causes other than PNH have been excluded prior to commencing treatment with ravulizumab; OR
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with ravulizumab, **AND**
- The treatment must not be in combination with eculizumab.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

Population criteria:

- Patient must be aged 18 years or over.

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

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested.

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

- (i) Haemoglobin (g/L)
- (ii) Platelets (x10⁹/L)
- (iii) White Cell Count (x10⁹/L)
- (iv) Reticulocytes (x10⁹/L)
- (v) Neutrophils (x10⁹/L)
- (vi) Granulocyte clone size (%)
- (vii) Lactate Dehydrogenase (LDH) and the upper limit of normal (ULN) for the reporting laboratory
- (viii) Multiple of LDH, ULN

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'First Continuing Treatment' criteria.

Note This grandfather restriction will cease to operate from 5 years after the date specified in the clinical criteria.

Authority required

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: First Continuing Treatment

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug for this condition under an 'Initial' or 'Grandfather' treatment criteria, **AND**
- The treatment must not be in combination with eculizumab.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

Population criteria:

- Patient must be aged 18 years or over.

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

- (1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested.

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

- (i) Haemoglobin (g/L)
- (ii) Platelets ($\times 10^9/L$)
- (iii) White Cell Count ($\times 10^9/L$)
- (iv) Reticulocytes ($\times 10^9/L$)
- (v) Neutrophils ($\times 10^9/L$)
- (vi) Granulocyte clone size (%)
- (vii) Lactate Dehydrogenase (LDH) and the upper limit of normal (ULN) for the reporting laboratory
- (viii) Multiple of LDH , ULN

Authority required

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Subsequent Continuing Treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the 'First Continuing Treatment' or 'Return' criteria, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, **AND**
- The treatment must not be in combination with eculizumab.

Treatment criteria:

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

Population criteria:

- Patient must be aged 18 years or over.

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

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested.

ravulizumab 1.1 g/11 mL injection, 11 mL vial

12883C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	25217.76	Ultomiris [XI]

ravulizumab 300 mg/3 mL injection, 3 mL vial

12884D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	6877.57	Ultomiris [XI]

▪ **RITUXIMAB**

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

Note Pharmaceutical benefits that have the form rituximab 100 mg/10 mL injection, 2 x 10 mL vials and pharmaceutical benefits that have the form rituximab 100 mg/10 mL injection, 10 mL vial are equivalent for the purposes of substitution.

Note Risk of end-organ damage or mortality includes a minimum of one of the following: Glomerulonephritis with risk of progression

- Risk to sight including scleritis/episcleritis, sudden visual loss, uveitis, retinal changes (vasculitis/thrombosis/exudates/haemorrhage)
- Bronchial/subglottic obstruction
- Pulmonary haemorrhage
- Parenchymal lung disease
- Sensory neural hearing loss
- Recurrent sinonasal disease requiring recurrent surgical interventions
- Meningitis, organic confusion, seizures, stroke, cord lesion, cranial nerve palsy, sensory peripheral neuropathy, motor mononeuritis multiplex

Note Patients could be considered contraindicated, refractory, or unable to tolerate cyclophosphamide for one of the following reasons: Cyclophosphamide is contraindicated as per the TGA approved Product Information;

- Cyclophosphamide is not recommended due to the need to preserve gonad function;
- Patient experiences severe toxicity to cyclophosphamide that warrants cessation of treatment;
- Patient has life- or organ-threatening deterioration at any time during treatment with cyclophosphamide, where the deterioration is thought to be due to severe uncontrolled active vasculitis;

- Commencing a further treatment cycle with cyclophosphamide would exceed the maximum cumulative dose of cyclophosphamide of 25g; or
- Patient's condition with this indication is persistent despite at least 3 months therapy with cyclophosphamide.

Authority required (STREAMLINED)

9336

Severe active granulomatosis with polyangiitis (Wegeners granulomatosis)

Treatment Phase: Re-induction of remission

Clinical criteria:

- The treatment must be for the re-induction of remission, **AND**
- Patient must have previously received and responded to this drug for this condition, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance of remission

Authority required (STREAMLINED)

9539

Severe active microscopic polyangiitis

Treatment Phase: Re-induction of remission

Clinical criteria:

- The treatment must be for the re-induction of remission, **AND**
- Patient must have previously received and responded to this drug for this condition, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance therapy.

rituximab 100 mg/10 mL injection, 10 mL vial

13001G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	..	..	*407.76	^a Ruxience [PF]

rituximab 100 mg/10 mL injection, 2 x 10 mL vials

11813R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*407.76	^a Riximyo [SZ]	^a Truxima [EW]

▪ RITUXIMAB

Note Pharmaceutical benefits that have the form rituximab 100 mg/10 mL injection, 2 x 10 mL vials and pharmaceutical benefits that have the form rituximab 100 mg/10 mL injection, 10 mL vial are equivalent for the purposes of substitution.

Note Risk of end-organ damage or mortality includes a minimum of one of the following: Glomerulonephritis with risk of progression

- Risk to sight including scleritis/episcleritis, sudden visual loss, uveitis, retinal changes (vasculitis/thrombosis/exudates/haemorrhage)
- Bronchial/subglottic obstruction
- Pulmonary haemorrhage
- Parenchymal lung disease
- Sensory neural hearing loss
- Recurrent sinonasal disease requiring recurrent surgical interventions
- Meningitis, organic confusion, seizures, stroke, cord lesion, cranial nerve palsy, sensory peripheral neuropathy, motor mononeuritis multiplex

Note Patients could be considered contraindicated, refractory, or unable to tolerate cyclophosphamide for one of the following reasons: Cyclophosphamide is contraindicated as per the TGA approved Product Information;

- Cyclophosphamide is not recommended due to the need to preserve gonad function;
- Patient experiences severe toxicity to cyclophosphamide that warrants cessation of treatment;
- Patient has life- or organ-threatening deterioration at any time during treatment with cyclophosphamide, where the deterioration is thought to be due to severe uncontrolled active vasculitis;
- Commencing a further treatment cycle with cyclophosphamide would exceed the maximum cumulative dose of cyclophosphamide of 25g; or
- Patient's condition with this indication is persistent despite at least 3 months therapy with cyclophosphamide.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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.

Authority required

Severe active granulomatosis with polyangiitis (Wegeners granulomatosis)

Treatment Phase: Induction of remission

Clinical criteria:

- The treatment must be for the induction of remission, **AND**
- Patient must not have previously received this drug for this condition, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance of remission

The authority application must be made in writing

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand, Riximyo or Truxima, is encouraged for treatment naive patients.

Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Authority required

Severe active microscopic polyangiitis

Treatment Phase: Induction of remission

Clinical criteria:

- The treatment must be for the induction of remission, **AND**
- Patient must not have previously received this drug for this condition, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance therapy.

The authority application must be made in writing

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand, Riximyo or Truxima, is encouraged for treatment naive patients.

Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Authority required

Severe active granulomatosis with polyangiitis (Wegeners granulomatosis)

Treatment Phase: Re-induction of remission

Clinical criteria:

- The treatment must be for the re-induction of remission, **AND**
- Patient must have previously received and responded to this drug for this condition, **AND**
- The treatment must in combination with glucocorticoids, **AND**
- Patient must be at risk of end-organ damage or mortality, **AND**
- Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.

Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.

This drug is not PBS-subsidised for maintenance of remission

The authority application must be made in writing

Authority required

Severe active microscopic polyangiitis

Treatment Phase: Re-induction of remission

Clinical criteria:

- The treatment must be for the re-induction of remission, **AND**
- Patient must have previously received and responded to this drug for this condition, **AND**

- The treatment must in combination with glucocorticoids, **AND**
 - Patient must be at risk of end-organ damage or mortality, **AND**
 - Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.
- Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.
- This drug is not PBS-subsidised for maintenance therapy.
- The authority application must be made in writing

rituximab 100 mg/10 mL injection, 10 mL vial

12997C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	..	..	*135.92	^a Ruxience [PF]

rituximab 100 mg/10 mL injection, 2 x 10 mL vials

10591K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	135.92	^a Riximyo [SZ]	^a Truxima [EW]

Highly Specialised Drugs Program (Community Access)

■ CLOZAPINE

Note Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed: Novartis Clozaril Patient Monitoring System (eCPMS), Pfizer ClopineCentral or Juno Connected Clozitor.

Authority required (STREAMLINED)

4998

Schizophrenia

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a psychiatrist; OR
- Must be treated by an authorised medical practitioner, with the agreement of the treating psychiatrist.

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy with this drug for this condition, **AND**
 - Patient must have completed at least 18 weeks therapy, **AND**
 - Patient must be on a clozapine dosage considered stable by a treating psychiatrist, **AND**
 - The treatment must be under the supervision and direction of a psychiatrist reviewing the patient at regular intervals.
- A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

clozapine 50 mg/mL oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10341G	1	..	..	148.18	42.50	Clopine Suspension [PF]

clozapine 100 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
10358E	2	..	..	*259.86	42.50	Clopine 100 [PF] Clozitor [JU]	Clozaril 100 [GO]

clozapine 200 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
10288L	2	..	..	*511.94	42.50	Clopine 200 [PF]	Clozitor [JU]

clozapine 25 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
10289M	2	..	..	*76.42	42.50	Clopine 25 [PF] Clozitor [JU]	Clozaril 25 [GO]

clozapine 50 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
10302F	2	..	..	*142.24	42.50	Clopine 50 [PF]	Clozitor [JU]