Australian Government
Department of Health and Aged Care

PBS

Schedule of Pharmaceutical Benefits

Summary of Changes

Effective 1 January 2023

Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 January 2023 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	$7.82
	Dangerous drug fee	$4.84
	Extemporaneously-prepared	$9.86
	Allowable additional patient charge*	$3.29
Additional Fees (for safety net prices):	Ready-prepared	$1.31
	Extemporaneously-prepared	$1.68
Patient Co-payments:	General	$30.00
	Concessional	$7.30
Safety Net Thresholds:	General	$1563.50
	Concessional	$262.80
Safety Net Card Issue Fee:		$11.42

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

Summary of Changes

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 January 2023. The Schedule is updated on the first day of each month and is available on the internet at www.pbs.gov.au.

Prescriber Bag

Advance Notices

1 February 2023

Deletion – Brand

3497C *APO-Salbutamol, TX* – **SALBUTAMOL**, salbutamol 5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules

1 April 2023

Deletion – Brand

3479D *DBL Morphine Sulfate Pentahydrate, PF* – **MORPHINE**, morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules

3480E *DBL Morphine Sulfate Pentahydrate, PF* – **MORPHINE**, morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules

General Pharmaceutical Benefits

Additions

Addition – Item

13200R **BECLOMETASONE + FORMOTEROL (EFORMOTEROL) + GLYCOPYRRONIUM**, beclometasone dipropionate 200 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation + glycopyrronium 10 microgram/actuation inhalation, 120 actuations *(Trimbow)*

13199Q **DARATUMUMAB**, daratumumab 1.8 g/15 mL injection, 15 mL vial *(Darzalex SC)*

13202W **DARATUMUMAB**, daratumumab 1.8 g/15 mL injection, 15 mL vial *(Darzalex SC)*

13177M **FARICIMAB**, faricimab 28.8 mg/0.24 mL injection, 0.24 mL vial *(Vabysmo)*

13183W **FARICIMAB**, faricimab 28.8 mg/0.24 mL injection, 0.24 mL vial *(Vabysmo)*

13195L **FARICIMAB**, faricimab 28.8 mg/0.24 mL injection, 0.24 mL vial *(Vabysmo)*

13198P **FARICIMAB**, faricimab 28.8 mg/0.24 mL injection, 0.24 mL vial *(Vabysmo)*

11049M **SODIUM CHLORIDE + POTASSIUM CHLORIDE + GLUCOSE MONOHYDRATE + CITRIC ACID**, sodium chloride 470 mg + potassium chloride 300 mg (potassium 4 mmol) + glucose monohydrate 3.56 g + sodium acid citrate 530 mg powder for oral liquid, 10 x 4.9 g sachets *(O.R.S.)*

Addition – Brand

5542Q *Vizo-PF Dorzolatim, AE* – **DORZOLAMIDE + TIMOLOL**, dorzolamide 2% + timolol 0.5% eye drops, 5 mL

8567X *Vizo-PF Dorzolatim, AE* – **DORZOLAMIDE + TIMOLOL**, dorzolamide 2% + timolol 0.5% eye drops, 5 mL

9432K *Escitalopram Sandoz, HX* – **ESCITALOPRAM**, escitalopram 10 mg tablet, 28

9433L *Escitalopram Sandoz, HX* – **ESCITALOPRAM**, escitalopram 20 mg tablet, 28

8651H *Pharmacor Mycophenolate, CR* – **MYCOPHENOLATE**, mycophenolate mofetil 1 g/5 mL powder for oral liquid, 165 mL

10004M *Sunitinib MSN, LR* – **SUNITINIB**, sunitinib 12.5 mg capsule, 28

10009T *Sunitinib MSN, LR* – **SUNITINIB**, sunitinib 12.5 mg capsule, 28

11266Y *Sunitinib MSN, LR* – **SUNITINIB**, sunitinib 12.5 mg capsule, 28

9417P *Sunitinib MSN, LR* – **SUNITINIB**, sunitinib 12.5 mg capsule, 28

9420T *Sunitinib MSN, LR* – **SUNITINIB**, sunitinib 12.5 mg capsule, 28

9488J *Sunitinib MSN, LR* – **SUNITINIB**, sunitinib 12.5 mg capsule, 28

11253G *Sunitinib MSN, LR* – **SUNITINIB**, sunitinib 25 mg capsule, 28

2842N *Sunitinib MSN, LR* – **SUNITINIB**, sunitinib 25 mg capsule, 28

2959R *Sunitinib MSN, LR* – **SUNITINIB**, sunitinib 25 mg capsule, 28

9418Q *Sunitinib MSN, LR* – **SUNITINIB**, sunitinib 25 mg capsule, 28

9421W *Sunitinib MSN, LR* – **SUNITINIB**, sunitinib 25 mg capsule, 28

9489K *Sunitinib MSN, LR* – **SUNITINIB**, sunitinib 25 mg capsule, 28

10459L *Sunitinib MSN, LR* – **SUNITINIB**, sunitinib 37.5 mg capsule, 28

10464R *Sunitinib MSN, LR* – **SUNITINIB**, sunitinib 37.5 mg capsule, 28

10473F *Sunitinib MSN, LR* – **SUNITINIB**, sunitinib 37.5 mg capsule, 28

10503T *Sunitinib MSN, LR* – **SUNITINIB**, sunitinib 37.5 mg capsule, 28

10504W *Sunitinib MSN, LR* – **SUNITINIB**, sunitinib 37.5 mg capsule, 28

11256K *Sunitinib MSN, LR* – **SUNITINIB**, sunitinib 37.5 mg capsule, 28

10010W *Sunitinib MSN, LR* – **SUNITINIB**, sunitinib 50 mg capsule, 28

11250D *Sunitinib MSN, LR* – **SUNITINIB**, sunitinib 50 mg capsule, 28

2837H *Sunitinib MSN, LR* – **SUNITINIB**, sunitinib 50 mg capsule, 28

9419R *Sunitinib MSN, LR* – **SUNITINIB**, sunitinib 50 mg capsule, 28

9422X *Sunitinib MSN, LR* – **SUNITINIB**, sunitinib 50 mg capsule, 28

9490L *Sunitinib MSN, LR* – **SUNITINIB**, sunitinib 50 mg capsule, 28

Addition – Equivalence Indicator

8651H *CellCept, RO* – **MYCOPHENOLATE**, mycophenolate mofetil 1 g/5 mL powder for oral liquid, 165 mL

Addition – Note

12910L **MOLNUPIRAVIR**, molnupiravir 200 mg capsule, 40 *(Lagevrio)*

Deletions

Deletion – Brand

8245Y *Fera, AS* – **LETROZOLE**, letrozole 2.5 mg tablet, 30

1746X *Mendeleev Paracetamol, HX* – **PARACETAMOL**, paracetamol 500 mg tablet, 100

5196L *Mendeleev Paracetamol, HX* – **PARACETAMOL**, paracetamol 500 mg tablet, 100

5224Y *Mendeleev Paracetamol, HX* – **PARACETAMOL**, paracetamol 500 mg tablet, 100

8784H *Mendeleev Paracetamol, HX* – **PARACETAMOL**, paracetamol 500 mg tablet, 100

12001P *Biaxsig, AV* – **ROXITHROMYCIN**, roxithromycin 150 mg tablet, 10

12001P *Rulide, SW* – **ROXITHROMYCIN**, roxithromycin 150 mg tablet, 10

1760P *Biaxsig, AV* – **ROXITHROMYCIN**, roxithromycin 150 mg tablet, 10

1760P *Rulide, SW* – **ROXITHROMYCIN**, roxithromycin 150 mg tablet, 10

5260W *Biaxsig, AV* – **ROXITHROMYCIN**, roxithromycin 150 mg tablet, 10

5260W *Rulide, SW* – **ROXITHROMYCIN**, roxithromycin 150 mg tablet, 10

11993F *Biaxsig, AV* – **ROXITHROMYCIN**, roxithromycin 300 mg tablet, 5

5261X *Biaxsig, AV* – **ROXITHROMYCIN**, roxithromycin 300 mg tablet, 5

8016X *Biaxsig, AV* – **ROXITHROMYCIN**, roxithromycin 300 mg tablet, 5

Deletion – Note

2856H **PHENELZINE**, phenelzine 15 mg tablet, 100 *(Nardil)*

Alterations

Alteration – Restriction

12667Q **BROLUCIZUMAB**, brolucizumab 6 mg/0.05 mL intraocular injection, 0.05 mL syringe *(Beovu)*

12683M **DARATUMUMAB**, daratumumab 1.8 g/15 mL injection, 15 mL vial *(Darzalex SC)*

5449T **LEFLUNOMIDE**, leflunomide 10 mg tablet, 30 *(Arabloc, Arava, Ataris 10, Leflunomide APOTEX, Leflunomide Sandoz, Leflunomide generichealth)*

8374R **LEFLUNOMIDE**, leflunomide 10 mg tablet, 30 *(Arabloc, Arava, Ataris 10, Leflunomide APOTEX, Leflunomide Sandoz, Leflunomide generichealth, Lunava 10)*

5450W **LEFLUNOMIDE**, leflunomide 20 mg tablet, 30 *(Arava, Ataris 20, Leflunomide APOTEX, Leflunomide Sandoz, Leflunomide generichealth)*

8375T **LEFLUNOMIDE**, leflunomide 20 mg tablet, 30 *(Arava, Ataris 20, Leflunomide APOTEX, Leflunomide Sandoz, Leflunomide generichealth, Lunava 20)*

12910L **MOLNUPIRAVIR**, molnupiravir 200 mg capsule, 40 *(Lagevrio)*

12996B **NIRMATRELVIR (&) RITONAVIR**, nirmatrelvir 150 mg tablet [4] (&) ritonavir 100 mg tablet [2], 5 x 6 *(Paxlovid)*

Alteration – Restriction Level

		From	*To*
5449T	**LEFLUNOMIDE**, leflunomide 10 mg tablet, 30 *(Arabloc, Arava, Ataris 10, Leflunomide APOTEX, Leflunomide Sandoz, Leflunomide generichealth)*	streamlined	restricted
8374R	**LEFLUNOMIDE**, leflunomide 10 mg tablet, 30 *(Arabloc, Arava, Ataris 10, Leflunomide APOTEX, Leflunomide Sandoz, Leflunomide generichealth, Lunava 10)*	streamlined	restricted
5450W	**LEFLUNOMIDE**, leflunomide 20 mg tablet, 30 *(Arava, Ataris 20, Leflunomide APOTEX, Leflunomide Sandoz, Leflunomide generichealth)*	streamlined	restricted
8375T	**LEFLUNOMIDE**, leflunomide 20 mg tablet, 30 *(Arava, Ataris 20, Leflunomide APOTEX, Leflunomide Sandoz, Leflunomide generichealth, Lunava 20)*	streamlined	restricted

Alteration – Manufacturer Code

		From	*To*
8179L	*Anastrol* – **ANASTROZOLE**, anastrozole 1 mg tablet, 30	AS	TB

Supply Only

When a product is deleted from the Schedule it may be available under Supply Only rules. Supply Only items/brands are available on the Schedule for dispensing but not for prescribing, usually for a period of up to 12 months from when it is deleted.

Substitution of Supply Only items/brands with products flagged as “equivalent for substitution” still apply as specified in the Schedule at the time the script was written.

Further information on Supply Only arrangements is available at www.pbs.gov.au

Supply Only Commencing 1 January 2023

11564P **ERTUGLIFLOZIN + METFORMIN**, ertugliflozin 2.5 mg + metformin hydrochloride 1 g tablet, 56 *(Segluromet 2.5/1000)*

11581M **ERTUGLIFLOZIN + METFORMIN**, ertugliflozin 2.5 mg + metformin hydrochloride 1 g tablet, 56 *(Segluromet 2.5/1000)*

11575F **ERTUGLIFLOZIN + METFORMIN**, ertugliflozin 2.5 mg + metformin hydrochloride 500 mg tablet, 56 *(Segluromet 2.5/500)*

11584Q **ERTUGLIFLOZIN + METFORMIN**, ertugliflozin 2.5 mg + metformin hydrochloride 500 mg tablet, 56 *(Segluromet 2.5/500)*

11563N **ERTUGLIFLOZIN + METFORMIN**, ertugliflozin 7.5 mg + metformin hydrochloride 1 g tablet, 56 *(Segluromet 7.5/1000)*

11569X **ERTUGLIFLOZIN + METFORMIN**, ertugliflozin 7.5 mg + metformin hydrochloride 1 g tablet, 56 *(Segluromet 7.5/1000)*

11562M **ERTUGLIFLOZIN + METFORMIN**, ertugliflozin 7.5 mg + metformin hydrochloride 500 mg tablet, 56 *(Segluromet 7.5/500)*

11568W **ERTUGLIFLOZIN + METFORMIN**, ertugliflozin 7.5 mg + metformin hydrochloride 500 mg tablet, 56 *(Segluromet 7.5/500)*

Advance Notices

1 February 2023

Deletion – Brand

3423E *Byetta 5 microgram, AP* – **EXENATIDE**, exenatide 5 microgram/0.02 mL injection, 1.2 mL pen device

3424F *Byetta 10 microgram, AP* – **EXENATIDE**, exenatide 10 microgram/0.04 mL injection, 2.4 mL pen device

1692C *ARX-Nitrofurantoin, XT* – **NITROFURANTOIN**, nitrofurantoin 50 mg capsule, 30

1693D *ARX-Nitrofurantoin, XT* – **NITROFURANTOIN**, nitrofurantoin 100 mg capsule, 30

2001H *APO-Salbutamol, TX* – **SALBUTAMOL**, salbutamol 5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules

8885P *Imigran FDT, AS* – **SUMATRIPTAN**, SUMATRIPTAN Tablet (fast disintegrating) 50 mg (as succinate), 2

1 March 2023

Deletion – Brand

1750D *Ircal, PE* – **PARAFFIN**, paraffin 1 g/g eye ointment, 2 x 3.5 g

5522P *Ircal, PE* – **PARAFFIN**, paraffin 1 g/g eye ointment, 2 x 3.5 g

9218E *Ircal, PE* – **PARAFFIN**, paraffin 1 g/g eye ointment, 2 x 3.5 g

1897W *Feldene, PF* – **PIROXICAM**, piroxicam 10 mg capsule, 50

5203W *Feldene, PF* – **PIROXICAM**, piroxicam 10 mg capsule, 50

1 April 2023

Deletion – Brand

9092M *Strattera, LY* – **ATOMOXETINE**, atomoxetine 10 mg capsule, 28

9093N *Strattera, LY* – **ATOMOXETINE**, atomoxetine 18 mg capsule, 28

9094P *Strattera, LY* – **ATOMOXETINE**, atomoxetine 25 mg capsule, 28

9095Q *Strattera, LY* – **ATOMOXETINE**, atomoxetine 40 mg capsule, 28

9096R *Strattera, LY* – **ATOMOXETINE**, atomoxetine 60 mg capsule, 28

9289X *Strattera, LY* – **ATOMOXETINE**, atomoxetine 80 mg capsule, 28

9290Y *Strattera, LY* – **ATOMOXETINE**, atomoxetine 100 mg capsule, 28

9299K *Jurnista, JC* – **HYDROMORPHONE**, hydromorphone hydrochloride 4 mg modified release tablet, 14

9406C *Jurnista, JC* – **HYDROMORPHONE**, hydromorphone hydrochloride 8 mg modified release tablet, 14

9407D *Jurnista, JC* – **HYDROMORPHONE**, hydromorphone hydrochloride 16 mg modified release tablet, 14

9408E *Jurnista, JC* – **HYDROMORPHONE**, hydromorphone hydrochloride 32 mg modified release tablet, 14

9409F *Jurnista, JC* – **HYDROMORPHONE**, hydromorphone hydrochloride 64 mg modified release tablet, 14

2436F *Natrilix, SE* – **INDAPAMIDE**, indapamide hemihydrate 2.5 mg tablet, 90

8196J *Sporanox, JC* – **ITRACONAZOLE**, itraconazole 100 mg capsule, 60

1644M *DBL Morphine Sulfate Pentahydrate, PF* – **MORPHINE**, morphine sulfate pentahydrate 10 mg/mL injection, 5 x 1 mL ampoules

1645N *DBL Morphine Sulfate Pentahydrate, PF* – **MORPHINE**, morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules

1647Q *DBL Morphine Sulfate Pentahydrate, PF* – **MORPHINE**, morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules

5168B *DBL Morphine Sulfate Pentahydrate, PF* – **MORPHINE**, morphine sulfate pentahydrate 10 mg/mL injection, 5 x 1 mL ampoules

5169C *DBL Morphine Sulfate Pentahydrate, PF* – **MORPHINE**, morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules

5170D *DBL Morphine Sulfate Pentahydrate, PF* – **MORPHINE**, morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules

1 August 2023
Deletion – Brand

2418G *Amitriptyline Alphapharm 25, MQ* – **AMITRIPTYLINE**, amitriptyline hydrochloride 25 mg tablet, 50

1358L *Dosulepin Mylan, MQ* – **DOSULEPIN (DOTHIEPIN)**, dosulepin (dothiepin) hydrochloride 75 mg tablet, 30

1500Y *Hydrocortisone Mylan 20, MQ* – **HYDROCORTISONE**, hydrocortisone 20 mg tablet, 60

Palliative Care

Advance Notices

1 April 2023
Deletion – Brand

12473L *Jurnista, JC* – **HYDROMORPHONE**, hydromorphone hydrochloride 16 mg modified release tablet, 14

12482Y *Jurnista, JC* – **HYDROMORPHONE**, hydromorphone hydrochloride 8 mg modified release tablet, 14

12496Q *Jurnista, JC* – **HYDROMORPHONE**, hydromorphone hydrochloride 4 mg modified release tablet, 14

12535R *Jurnista, JC* – **HYDROMORPHONE**, hydromorphone hydrochloride 64 mg modified release tablet, 14

12543E *Jurnista, JC* – **HYDROMORPHONE**, hydromorphone hydrochloride 32 mg modified release tablet, 14

12499W *DBL Morphine Sulfate Pentahydrate, PF* – **MORPHINE**, morphine sulfate pentahydrate 10 mg/mL injection, 5 x 1 mL ampoules

12503C *DBL Morphine Sulfate Pentahydrate, PF* – **MORPHINE**, morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules

12548K *DBL Morphine Sulfate Pentahydrate, PF* – **MORPHINE**, morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules

Highly Specialised Drugs Program (Private Hospital)

Additions

Addition – Brand

6364Y *Pharmacor Mycophenolate, CR* – **MYCOPHENOLATE**, mycophenolate mofetil 1 g/5 mL powder for oral liquid, 165 mL

6371H *Zoledronic Acid Accord, OC* – **ZOLEDRONIC ACID**, zoledronic acid 4 mg/5 mL injection, 5 mL vial

Addition – Equivalence Indicator

6364Y *CellCept, RO* – **MYCOPHENOLATE**, mycophenolate mofetil 1 g/5 mL powder for oral liquid, 165 mL

Addition – Note

10417G **POMALIDOMIDE**, pomalidomide 3 mg capsule, 21 *(Pomalidomide Sandoz, Pomalyst, Pomolide)*

12668R **POMALIDOMIDE**, pomalidomide 3 mg capsule, 14 *(Pomalidomide Sandoz, Pomalyst, Pomolide)*

10386P **POMALIDOMIDE**, pomalidomide 4 mg capsule, 21 *(Pomalidomide Sandoz, Pomalyst, Pomolide)*

12661J **POMALIDOMIDE**, pomalidomide 4 mg capsule, 14 *(Pomalidomide Sandoz, Pomalyst, Pomolide)*

Deletions

Deletion – Equivalence Indicator

10417G *Pomalidomide Sandoz, SZ* – **POMALIDOMIDE**, pomalidomide 3 mg capsule, 21

10417G *Pomalyst, CJ* – **POMALIDOMIDE**, pomalidomide 3 mg capsule, 21

10417G *Pomolide, JU* – **POMALIDOMIDE**, pomalidomide 3 mg capsule, 21

12668R *Pomalidomide Sandoz, SZ* – **POMALIDOMIDE**, pomalidomide 3 mg capsule, 14

12668R *Pomalyst, CJ* – **POMALIDOMIDE**, pomalidomide 3 mg capsule, 14

12668R *Pomolide, JU* – **POMALIDOMIDE**, pomalidomide 3 mg capsule, 14

10386P *Pomalidomide Sandoz, SZ* – **POMALIDOMIDE**, pomalidomide 4 mg capsule, 21

10386P *Pomalyst, CJ* – **POMALIDOMIDE**, pomalidomide 4 mg capsule, 21

10386P *Pomolide, JU* – **POMALIDOMIDE**, pomalidomide 4 mg capsule, 21

12661J *Pomalidomide Sandoz, SZ* – **POMALIDOMIDE**, pomalidomide 4 mg capsule, 14

12661J *Pomalyst, CJ* – **POMALIDOMIDE**, pomalidomide 4 mg capsule, 14

12661J *Pomolide, JU* – **POMALIDOMIDE**, pomalidomide 4 mg capsule, 14

Alterations

Alteration – Note

5827Q **ELTROMBOPAG**, eltrombopag 25 mg tablet, 28 *(Revolade)*

5828R **ELTROMBOPAG**, eltrombopag 50 mg tablet, 28 *(Revolade)*

9697J **ROMIPLOSTIM**, romiplostim 250 microgram injection, 1 vial *(Nplate)*

9699L **ROMIPLOSTIM**, romiplostim 500 microgram injection, 1 vial *(Nplate)*

Alteration – Restriction

5827Q **ELTROMBOPAG**, eltrombopag 25 mg tablet, 28 *(Revolade)*

5828R **ELTROMBOPAG**, eltrombopag 50 mg tablet, 28 *(Revolade)*

10417G **POMALIDOMIDE**, pomalidomide 3 mg capsule, 21 *(Pomalidomide Sandoz, Pomalyst, Pomolide)*

12668R **POMALIDOMIDE**, pomalidomide 3 mg capsule, 14 *(Pomalidomide Sandoz, Pomalyst, Pomolide)*

10386P **POMALIDOMIDE**, pomalidomide 4 mg capsule, 21 *(Pomalidomide Sandoz, Pomalyst, Pomolide)*

12661J **POMALIDOMIDE**, pomalidomide 4 mg capsule, 14 *(Pomalidomide Sandoz, Pomalyst, Pomolide)*

9697J **ROMIPLOSTIM**, romiplostim 250 microgram injection, 1 vial *(Nplate)*

9699L **ROMIPLOSTIM**, romiplostim 500 microgram injection, 1 vial *(Nplate)*

Alteration – Number of Repeats

		From	*To*
9697J	**ROMIPLOSTIM**, romiplostim 250 microgram injection, 1 vial *(Nplate)*	0	5
9699L	**ROMIPLOSTIM**, romiplostim 500 microgram injection, 1 vial *(Nplate)*	0	5

Highly Specialised Drugs Program (Public Hospital)

Additions

Addition – Brand

9500B *Pharmacor Mycophenolate, CR* – **MYCOPHENOLATE**, mycophenolate mofetil 1 g/5 mL powder for oral liquid, 165 mL

9653C *Zoledronic Acid Accord, OC* – **ZOLEDRONIC ACID**, zoledronic acid 4 mg/5 mL injection, 5 mL vial

Addition – Equivalence Indicator

9500B *CellCept, RO* – **MYCOPHENOLATE**, mycophenolate mofetil 1 g/5 mL powder for oral liquid, 165 mL

Addition – Note

10406Q **POMALIDOMIDE**, pomalidomide 3 mg capsule, 21 *(Pomalidomide Sandoz, Pomalyst, Pomolide)*

12666P **POMALIDOMIDE**, pomalidomide 3 mg capsule, 14 *(Pomalidomide Sandoz, Pomalyst, Pomolide)*

10387Q **POMALIDOMIDE**, pomalidomide 4 mg capsule, 21 *(Pomalidomide Sandoz, Pomalyst, Pomolide)*

12665N **POMALIDOMIDE**, pomalidomide 4 mg capsule, 14 *(Pomalidomide Sandoz, Pomalyst, Pomolide)*

Deletions

Deletion – Equivalence Indicator

10406Q *Pomalidomide Sandoz, SZ* – **POMALIDOMIDE**, pomalidomide 3 mg capsule, 21

10406Q *Pomalyst, CJ* – **POMALIDOMIDE**, pomalidomide 3 mg capsule, 21

10406Q *Pomolide, JU* – **POMALIDOMIDE**, pomalidomide 3 mg capsule, 21

12666P *Pomalidomide Sandoz, SZ* – **POMALIDOMIDE**, pomalidomide 3 mg capsule, 14

12666P *Pomalyst, CJ* – **POMALIDOMIDE**, pomalidomide 3 mg capsule, 14

12666P *Pomolide, JU* – **POMALIDOMIDE**, pomalidomide 3 mg capsule, 14

10387Q *Pomalidomide Sandoz, SZ* – **POMALIDOMIDE**, pomalidomide 4 mg capsule, 21

10387Q *Pomalyst, CJ* – **POMALIDOMIDE**, pomalidomide 4 mg capsule, 21

10387Q *Pomolide, JU* – **POMALIDOMIDE**, pomalidomide 4 mg capsule, 21

12665N *Pomalidomide Sandoz, SZ* – **POMALIDOMIDE**, pomalidomide 4 mg capsule, 14

12665N *Pomalyst, CJ* – **POMALIDOMIDE**, pomalidomide 4 mg capsule, 14

12665N *Pomolide, JU* – **POMALIDOMIDE**, pomalidomide 4 mg capsule, 14

Alterations

Alteration – Note

5825N **ELTROMBOPAG**, eltrombopag 25 mg tablet, 28 *(Revolade)*

5826P **ELTROMBOPAG**, eltrombopag 50 mg tablet, 28 *(Revolade)*

9696H **ROMIPLOSTIM**, romiplostim 250 microgram injection, 1 vial *(Nplate)*

9698K **ROMIPLOSTIM**, romiplostim 500 microgram injection, 1 vial *(Nplate)*

Alteration – Restriction

5825N **ELTROMBOPAG**, eltrombopag 25 mg tablet, 28 *(Revolade)*

5826P **ELTROMBOPAG**, eltrombopag 50 mg tablet, 28 *(Revolade)*

10406Q **POMALIDOMIDE**, pomalidomide 3 mg capsule, 21 *(Pomalidomide Sandoz, Pomalyst, Pomolide)*

12666P **POMALIDOMIDE**, pomalidomide 3 mg capsule, 14 *(Pomalidomide Sandoz, Pomalyst, Pomolide)*

10387Q **POMALIDOMIDE**, pomalidomide 4 mg capsule, 21 *(Pomalidomide Sandoz, Pomalyst, Pomolide)*

12665N **POMALIDOMIDE**, pomalidomide 4 mg capsule, 14 *(Pomalidomide Sandoz, Pomalyst, Pomolide)*

9696H **ROMIPLOSTIM**, romiplostim 250 microgram injection, 1 vial *(Nplate)*

9698K **ROMIPLOSTIM**, romiplostim 500 microgram injection, 1 vial *(Nplate)*

Alteration – Number of Repeats

		From	*To*
9696H	**ROMIPLOSTIM**, romiplostim 250 microgram injection, 1 vial *(Nplate)*	0	5
9698K	**ROMIPLOSTIM**, romiplostim 500 microgram injection, 1 vial *(Nplate)*	0	5

Repatriation Pharmaceutical Benefits

Deletions

Deletion – Brand

10582Y *Mendeleev Paracetamol, HX* – **PARACETAMOL**, paracetamol 500 mg tablet, 100

10585D *Mendeleev Paracetamol, HX* – **PARACETAMOL**, paracetamol 500 mg tablet, 100

▪ BECLOMETASONE + FORMOTEROL (EFORMOTEROL) + GLYCOPYRRONIUM

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

Note This product is not indicated for the initiation of treatment in asthma

Note This pharmaceutical benefit is not for the treatment of chronic obstructive pulmonary disease (COPD).

Note The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

Note A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

Authority required (STREAMLINED)

12603

Severe asthma

Clinical criteria:

- Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique.

Population criteria:

- Patient must be at least 18 years of age.

Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

beclometasone dipropionate 200 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation + glycopyrronium 10 microgram/actuation inhalation, 120 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13200R (NP)	‡1	5	..	87.52	30.00	Trimbow [EU]

▪ BROLUCIZUMAB

Note Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

Note No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

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

Note Special Pricing Arrangements apply.

Authority required

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- The condition must be due to age-related macular degeneration (AMD), **AND**
- Patient must have persistent macular exudation, as determined clinically and/or by optical coherence tomography or fluorescein angiography, despite at least 6 months of PBS-subsidised treatment with: 1. Aflibercept and/or 2. Ranibizumab and/or 3. Faricimab, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

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

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) 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).

All reports must be documented in the patient's medical records.

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 authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can 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

Authority required

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.

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).

brolucizumab 6 mg/0.05 mL intraocular injection, 0.05 mL syringe

12667Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	994.06	30.00	Beovu [NV]

▪ DARATUMUMAB

Note This drug is not PBS-subsidised for use in patients with multiple myeloma who have received two or more prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent, or, who are refractory to both a PI and an immunomodulatory agent, as monotherapy.

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

Note Special Pricing Arrangements apply.

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Initial treatment as second-line drug therapy for weeks 1 to 9 (administered once weekly)

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must be in combination with bortezomib and dexamethasone, **AND**
- Patient must have progressive disease after only one prior therapy (i.e. use must be as second-line drug therapy; use as third-line drug therapy or beyond is not PBS-subsidised).

Treatment criteria:

- Patient must be undergoing treatment with this drug in one of the following situations: (i) for the first time, irrespective of whether the diagnosis has been reclassified (i.e. the diagnosis has changed between multiple myeloma/amyloidosis), (ii) changing the drug's form (intravenous/subcutaneous) within the first 9 weeks of treatment for the same PBS indication.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Details of: the histological diagnosis of multiple myeloma; prior treatments including name(s) of drug(s) and date of most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and which disease activity parameters will be used to assess response, must be documented in the patient's medical records.

Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters must be used to determine response, results for either (a) or (b) or (c) should be documented for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) must be documented in the patient's medical records. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be documented in the patient's medical records.

A line of therapy is defined as 1 or more cycles of a planned treatment program. This may consist of 1 or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner.

A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse, or toxicity, with the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.

daratumumab 1.8 g/15 mL injection, 15 mL vial

12683M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	8	..	7171.56	30.00	Darzalex SC [JC]

▪ DARATUMUMAB

Note The intravenously administered presentation of this drug is not PBS listed for this indication at the request of the sponsor.

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

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

Note Special Pricing Arrangements apply.

Authority required

Newly diagnosed systemic light chain amyloidosis

Treatment Phase: Continuing treatment from week 25 onwards (administered once every four weeks)

Clinical criteria:

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

Treatment criteria:

- Must be treated by a haematologist (this does not exclude treatment via a multidisciplinary team, but the PBS authority application must be sought by the treating haematologist), **AND**
- Patient must be undergoing continuing treatment that does not extend treatment duration beyond whichever comes first: (i) disease progression, (ii) 96 cumulative weeks from the first administered dose, once in a lifetime.

daratumumab 1.8 g/15 mL injection, 15 mL vial

13199Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	7171.56	30.00	Darzalex SC [JC]

▪ DARATUMUMAB

Note The intravenously administered presentation of this drug is not PBS listed for this indication at the request of the sponsor.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 888 333.
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 authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can 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
PBS Authorities
GPO Box 9826
[Your capital city]

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

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

Note Special Pricing Arrangements apply.

Authority required

Newly diagnosed systemic light chain amyloidosis

Treatment Phase: Initial treatment from week 0 to week 24

Clinical criteria:

- The condition must have histological evidence consistent with a diagnosis of systemic light-chain amyloidosis, **AND**
- The condition must be untreated with drug therapy, including this drug, irrespective of whether the diagnosis has been reclassified (i.e. the diagnosis changes between multiple myeloma/amyloidosis), **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of no higher than 2 at treatment initiation.

Treatment criteria:

- Must be treated by a haematologist (this does not exclude treatment via a multidisciplinary team, but the PBS authority application must be sought by the treating haematologist), **AND**
- Patient must be undergoing concomitant treatment limited to each of: (i) bortezomib, (ii) cyclophosphamide, (iii) dexamethasone, at certain weeks of treatment as outlined in the drug's approved Product Information.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail, and must include:

Details of the histological evidence supporting the diagnosis of systemic light chain amyloidosis, limited to: (i) the date of the histology result, which is no older than 4 weeks at the time of making this authority application, (ii) the name of pathologist/pathology provider, (iii) the site of biopsy.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) 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).

Authority required

Newly diagnosed systemic light chain amyloidosis

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

Clinical criteria:

- Patient must be continuing treatment with this drug that was commenced as non-PBS-subsidised supply prior to 1 January 2023, **AND**
- The condition must have histological evidence consistent with a diagnosis of systemic light-chain amyloidosis, **AND**
- The condition must have been, prior to the first dose of the non-PBS-subsidised supply, untreated with drug therapy, including this drug, irrespective of whether the diagnosis had been reclassified (i.e. the diagnosis changes between multiple myeloma/amyloidosis), **AND**
- Patient must have had a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 2 at the time non-PBS supply was initiated.

Treatment criteria:

- Must be treated by a haematologist (this does not exclude treatment via a multidisciplinary team, but the PBS authority application must be sought by the treating haematologist), **AND**
- Patient must be undergoing concomitant treatment limited to each of: (i) bortezomib, (ii) cyclophosphamide, (iii) dexamethasone, at certain weeks of treatment as outlined in the drug's approved Product Information, **AND**
- Patient must be undergoing continuing treatment that does not extend treatment duration beyond whichever comes first: (i) disease progression, (ii) 96 cumulative weeks from the first administered dose, once in a lifetime.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail, and must include:

Details of the histological evidence supporting the diagnosis of systemic light chain amyloidosis, limited to: (i) the date of the histology result, which was within 4 weeks prior to the commencement of non-PBS-subsidised therapy, (ii) the name of pathologist/pathology provider, (iii) the site of biopsy.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) 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).

Determine an appropriate number of repeat prescriptions for this authority application in line with either:

(i) Where the patient has received less than 10 non-PBS-subsidised doses, prescribe a number of repeat prescriptions up to the balance of: 15 doses less the number of non-PBS-subsidised doses; or

(ii) Where the patient has received at least 10 non-PBS-subsidised doses, prescribe no more than 5 repeat prescriptions.

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.

daratumumab 1.8 g/15 mL injection, 15 mL vial

13202W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	15	..	7171.56	30.00	Darzalex SC [JC]

▪ FARICIMAB

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

Note No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

Note Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

Note Special Pricing Arrangements apply.

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).

Authority required (STREAMLINED)

13406

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.

faricimab 28.8 mg/0.24 mL injection, 0.24 mL vial

13195L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	932.76	30.00	Vabysmo [RO]

▪ FARICIMAB

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

Note No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

Note Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

Note Special Pricing Arrangements apply.

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).

Authority required (STREAMLINED)

13402

Diabetic macular oedema (DMO)

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

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

faricimab 28.8 mg/0.24 mL injection, 0.24 mL vial

13198P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	932.76	30.00	Vabysmo [RO]

▪ FARICIMAB

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

Note No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

Note Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

Note Special Pricing Arrangements apply.

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 authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can 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

Authority required

Diabetic macular oedema (DMO)

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

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

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

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) 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).

All reports must be documented in the patient's medical records.

Authority required

Diabetic macular oedema (DMO)

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

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- Patient must have visual impairment due to diabetic macular oedema, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 January 2023, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) 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).

All reports must be documented in the patient's medical records.

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

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

faricimab 28.8 mg/0.24 mL injection, 0.24 mL vial

13177M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	932.76	30.00	Vabysmo [RO]

▪ FARICIMAB

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

Note No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

Note Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application.

Note Special Pricing Arrangements apply.

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 authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can 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

Authority required

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

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

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

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) 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).

All reports must be documented in the patient's medical records.

Authority required

Subfoveal choroidal neovascularisation (CNV)

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

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 January 2023, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.

If the application is submitted through HPOS form upload or mail, it must include:

(a) A completed authority prescription form; and

(b) 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).

All reports must be documented in the patient's medical records.

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

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

faricimab 28.8 mg/0.24 mL injection, 0.24 mL vial

13183W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	932.76	30.00	Vabysmo [RO]

▪ LEFLUNOMIDE

Caution Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

Restricted benefit

Severe active psoriatic arthritis

Clinical criteria:

- Patient must have previously received, and failed to achieve an adequate response to, one or more disease modifying anti-rheumatic drugs including methotrexate; OR
- Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate, **AND**
- The treatment must be initiated by a physician.

leflunomide 10 mg tablet, 30

5449T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	28.59	29.90	[a] Arabloc [AV] [a] Ataris 10 [AF] [a] Leflunomide generichealth [HQ]	[a] Arava [SW] [a] Leflunomide APOTEX [GX] [a] Leflunomide Sandoz [SZ]

leflunomide 20 mg tablet, 30

5450W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	37.19	30.00	[a] Arava [SW] [a] Leflunomide APOTEX [GX] [a] Leflunomide Sandoz [SZ]	[a] Ataris 20 [AF] [a] Leflunomide generichealth [HQ]

▪ LEFLUNOMIDE

Caution Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

Restricted benefit

Severe active rheumatoid arthritis

Clinical criteria:

- Patient must have previously received, and failed to achieve an adequate response to, one or more disease modifying anti-rheumatic drugs including methotrexate; OR
- Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate, **AND**
- The treatment must be initiated by a physician.

leflunomide 10 mg tablet, 30

8374R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	28.59	29.90	[a] Arabloc [AV] [a] Ataris 10 [AF] [a] Leflunomide generichealth [HQ] [a] Lunava 10 [ZP]	[a] Arava [SW] [a] Leflunomide APOTEX [GX] [a] Leflunomide Sandoz [SZ]

leflunomide 20 mg tablet, 30

8375T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	37.19	30.00	[a] Arava [SW] [a] Leflunomide APOTEX [GX] [a] Leflunomide Sandoz [SZ]	[a] Ataris 20 [AF] [a] Leflunomide generichealth [HQ] [a] Lunava 20 [ZP]

▪ MOLNUPIRAVIR

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 drug should be considered for use only if nirmatrelvir (&) ritonavir is contraindicated or otherwise unsuitable.

Authority required (STREAMLINED)

13759

SARS-CoV-2 infection

Clinical criteria:

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset; OR
- The treatment must be initiated as soon as possible after a diagnosis is confirmed where asymptomatic.

Population criteria:

- Patient must be at least 70 years of age.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

Authority required (STREAMLINED)

13760

SARS-CoV-2 infection

Clinical criteria:

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**

- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- Patient must be moderately to severely immunocompromised, **AND**
- Patient must be at risk of progression to severe disease due to immunocompromised status, **AND**
- The treatment must be initiated within 5 days of symptom onset.

Population criteria:

- Patient must be at least 18 years of age.

For the purpose of administering this restriction, 'moderately to severely immunocompromised' patients are those with:

1. Any primary or acquired immunodeficiency including:

a. Haematologic neoplasms: leukaemias, lymphomas, myelodysplastic syndromes, multiple myeloma and other plasma cell disorders,

b. Post-transplant: solid organ (on immunosuppressive therapy), haematopoietic stem cell transplant (within 24 months),

c. Immunocompromised due to primary or acquired (HIV/AIDS) immunodeficiency; OR

2. Any significantly immunocompromising condition(s) where, in the last 3 months the patient has received:

a. Chemotherapy or whole body radiotherapy,

b. High-dose corticosteroids (at least 20 mg of prednisone per day, or equivalent) for at least 14 days in a month, or pulse corticosteroid therapy,

c. Biological agents and other treatments that deplete or inhibit B cell or T cell function (abatacept, anti-CD20 antibodies, BTK inhibitors, JAK inhibitors, sphingosine 1-phosphate receptor modulators, anti-CD52 antibodies, anti-complement antibodies, anti-thymocyte globulin),

d. Selected conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) including mycophenolate, methotrexate, leflunomide, azathioprine, 6-mercaptopurine (at least 1.5mg/kg/day), alkylating agents (e.g. cyclophosphamide, chlorambucil), and systemic calcineurin inhibitors (e.g. cyclosporin, tacrolimus); OR

3. Any significantly immunocompromising condition(s) where, in the last 12 months the patient has received an anti-CD20 monoclonal antibody treatment, but criterion 2c above is not met; OR

4. Others with very high-risk conditions including Down Syndrome, cerebral palsy, congenital heart disease, thalassemia, sickle cell disease and other haemoglobinopathies; OR

5. People with disability with multiple comorbidities and/or frailty.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

Authority required (STREAMLINED)

13748

SARS-CoV-2 infection

Clinical criteria:

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset.

Population criteria:

- Patient must be each of: (i) identify as Aboriginal or Torres Strait Islander, (ii) at least 30 years of age, (iii) at high risk.

For the purpose of administering this restriction, high risk is defined as the presence of at least one of the following conditions:

1. The patient is in residential aged care

2. The patient has disability with multiple comorbidities and/or frailty

3. Neurological conditions, including stroke and dementia and demyelinating conditions

4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease

5. Heart failure, coronary artery disease, cardiomyopathies

6. Obesity (BMI greater than 30 kg/m^2)

7. Diabetes type I or II, requiring medication for glycaemic control

8. Renal impairment (eGFR less than 60mL/min)

9. Cirrhosis

10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above

11. Past COVID-19 infection episode resulting in hospitalisation.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

Note The Modified Monash Model categorises an area according to geographical remoteness and town size. Details can be found at: https://www.health.gov.au/health-topics/rural-health-workforce/classifications/mmm

Authority required (STREAMLINED)

13765

SARS-CoV-2 infection

Clinical criteria:

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset.

Population criteria:

- Patient must be both: (i) at least 50 years of age, (ii) at high risk.

For the purpose of administering this restriction, high risk is defined as either a past COVID-19 infection episode resulting in hospitalisation, or the presence of at least two of the following conditions:

1. The patient is in residential aged care,

2. The patient has disability with multiple comorbidities and/or frailty,

3. Neurological conditions, including stroke and dementia and demyelinating conditions,

4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease,

5. Heart failure, coronary artery disease, cardiomyopathies,

6. Obesity (BMI greater than 30 kg/m^2),

7. Diabetes type I or II, requiring medication for glycaemic control,

8. Renal impairment (eGFR less than 60mL/min),

9. Cirrhosis, or

10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

Note The Modified Monash Model categorises an area according to geographical remoteness and town size. Details can be found at: https://www.health.gov.au/health-topics/rural-health-workforce/classifications/mmm

molnupiravir 200 mg capsule, 40

12910L (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	1101.39	30.00	Lagevrio [MK]

▪ NIRMATRELVIR (&) RITONAVIR

Caution Nirmatrelvir with ritonavir has significant drug-drug interactions. Please refer to the TGA approved Paxlovid Product Information. Prescribers and dispensers should carefully review a patient's concomitant medications including over-the-counter medications, herbal supplements, and recreational drugs.

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

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

Authority required (STREAMLINED)

13759

SARS-CoV-2 infection

Clinical criteria:

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset; OR
- The treatment must be initiated as soon as possible after a diagnosis is confirmed where asymptomatic.

Population criteria:

- Patient must be at least 70 years of age.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

Authority required (STREAMLINED)

13760

SARS-CoV-2 infection

Clinical criteria:

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- Patient must be moderately to severely immunocompromised, **AND**
- Patient must be at risk of progression to severe disease due to immunocompromised status, **AND**
- The treatment must be initiated within 5 days of symptom onset.

Population criteria:

- Patient must be at least 18 years of age.

For the purpose of administering this restriction, 'moderately to severely immunocompromised' patients are those with:

1. Any primary or acquired immunodeficiency including:

a. Haematologic neoplasms: leukaemias, lymphomas, myelodysplastic syndromes, multiple myeloma and other plasma cell disorders,

b. Post-transplant: solid organ (on immunosuppressive therapy), haematopoietic stem cell transplant (within 24 months),

c. Immunocompromised due to primary or acquired (HIV/AIDS) immunodeficiency; OR

2. Any significantly immunocompromising condition(s) where, in the last 3 months the patient has received:

a. Chemotherapy or whole body radiotherapy,

b. High-dose corticosteroids (at least 20 mg of prednisone per day, or equivalent) for at least 14 days in a month, or pulse corticosteroid therapy,

c. Biological agents and other treatments that deplete or inhibit B cell or T cell function (abatacept, anti-CD20 antibodies, BTK inhibitors, JAK inhibitors, sphingosine 1-phosphate receptor modulators, anti-CD52 antibodies, anti-complement antibodies, anti-thymocyte globulin),

d. Selected conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) including mycophenolate, methotrexate, leflunomide, azathioprine, 6-mercaptopurine (at least 1.5mg/kg/day), alkylating agents (e.g. cyclophosphamide, chlorambucil), and systemic calcineurin inhibitors (e.g. cyclosporin, tacrolimus); OR

3. Any significantly immunocompromising condition(s) where, in the last 12 months the patient has received an anti-CD20 monoclonal antibody treatment, but criterion 2c above is not met; OR

4. Others with very high-risk conditions including Down Syndrome, cerebral palsy, congenital heart disease, thalassemia, sickle cell disease and other haemoglobinopathies; OR

5. People with disability with multiple comorbidities and/or frailty.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

Authority required (STREAMLINED)

13748

SARS-CoV-2 infection

Clinical criteria:

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset.

Population criteria:

- Patient must be each of: (i) identify as Aboriginal or Torres Strait Islander, (ii) at least 30 years of age, (iii) at high risk.

For the purpose of administering this restriction, high risk is defined as the presence of at least one of the following conditions:

1. The patient is in residential aged care

2. The patient has disability with multiple comorbidities and/or frailty

3. Neurological conditions, including stroke and dementia and demyelinating conditions

4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease

5. Heart failure, coronary artery disease, cardiomyopathies

6. Obesity (BMI greater than 30 kg/m^2)

7. Diabetes type I or II, requiring medication for glycaemic control

8. Renal impairment (eGFR less than 60mL/min)

9. Cirrhosis

10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above

11. Past COVID-19 infection episode resulting in hospitalisation.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

Note The Modified Monash Model categorises an area according to geographical remoteness and town size. Details can be found at: https://www.health.gov.au/health-topics/rural-health-workforce/classifications/mmm

Authority required (STREAMLINED)

13765

SARS-CoV-2 infection

Clinical criteria:

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset.

Population criteria:

- Patient must be both: (i) at least 50 years of age, (ii) at high risk.

For the purpose of administering this restriction, high risk is defined as either a past COVID-19 infection episode resulting in hospitalisation, or the presence of at least two of the following conditions:

1. The patient is in residential aged care,

2. The patient has disability with multiple comorbidities and/or frailty,

3. Neurological conditions, including stroke and dementia and demyelinating conditions,

4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease,

5. Heart failure, coronary artery disease, cardiomyopathies,

6. Obesity (BMI greater than 30 kg/m^2),

7. Diabetes type I or II, requiring medication for glycaemic control,

8. Renal impairment (eGFR less than 60mL/min),

9. Cirrhosis, or

10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above.

Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.

For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.

Access to this drug through this restriction is permitted irrespective of vaccination status.

Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.

Note The Modified Monash Model categorises an area according to geographical remoteness and town size. Details can be found at: https://www.health.gov.au/health-topics/rural-health-workforce/classifications/mmm

nirmatrelvir 150 mg tablet [4] (&) ritonavir 100 mg tablet [2], 5 x 6

12996B NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	1113.99	30.00	Paxlovid [HD]

▪ SODIUM CHLORIDE + POTASSIUM CHLORIDE + GLUCOSE MONOHYDRATE + CITRIC ACID

Authority required

Rehydration in intestinal failure

sodium chloride 470 mg + potassium chloride 300 mg (potassium 4 mmol) + glucose monohydrate 3.56 g + sodium acid citrate 530 mg powder for oral liquid, 10 x 4.9 g sachets

11049M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
30	..	..	*158.72	30.00	O.R.S. [AF]

Highly Specialised Drugs Program (Private Hospital)

ELTROMBOPAG

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

Note Special Pricing Arrangements apply.

Authority required

Severe thrombocytopenia

Treatment Phase: Initial treatment - New patient

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4 weeks, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The following criteria indicate failure to achieve an adequate response to corticosteroid and/or immunoglobulin therapy and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

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

(1) a completed authority prescription form,

(2) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form, and

(3) details of a platelet count supporting the diagnosis of ITP.

All reports must be documented in the patient's medical records.

The platelet count must be no more than 4 weeks old at the time of application.

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

Authority required

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction if the patient has not had a treatment break, confirmed through a pathology report from an Approved Pathology Authority; OR
- Patient must have swapped treatment from romiplostim to this drug under the Balance of supply or change of therapy restriction and demonstrated a sustained response; OR
- Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, confirmed through a pathology report from an Approved Pathology Authority, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

For the purposes of this restriction, a sustained response is defined as the patient having the ability to maintain a platelet count sufficient to prevent clinically significant bleeding based on clinical assessment.

The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug and must be documented in the patient's medical records.

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

Severe thrombocytopenia

Treatment Phase: Second or Subsequent Continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction, **AND**
- Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

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

Severe thrombocytopenia

Treatment Phase: Balance of supply or change of therapy

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment restriction; OR
- Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction; OR
- Patient must have received insufficient therapy with this drug for this condition under the Second or Subsequent Continuing treatment restriction; OR
- Patient must be swapping therapy from romiplostim to this drug for this condition, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment under this restriction.

Patients receiving treatment with romiplostim may change to eltrombopag under this restriction.

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).

eltrombopag 25 mg tablet, 28

5827Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	1340.58	Revolade [NV]

eltrombopag 50 mg tablet, 28

5828R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	2633.34	Revolade [NV]

▪ POMALIDOMIDE

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

Note 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).

Note Patients receiving pomalidomide under the PBS listing must be registered in the risk management program relevant for the brand of pomalidomide being prescribed and dispensed: Pomolide - Juno's Pregnancy Prevention Program; Pomalyst - i-access program; Pomalidomide Sandoz - Pregnancy Prevention Program.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment with triple therapy (this drug, bortezomib and dexamethasone)

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy that is either: (i) lenalidomide monotherapy, (ii) contains lenalidomide, **AND**
- Patient must have undergone or be ineligible for a stem cell transplant.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment with triple therapy (this drug, bortezomib and dexamethasone)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

pomalidomide 3 mg capsule, 14

12668R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	1913.54	Pomalidomide Sandoz [SZ] Pomolide [JU]	Pomalyst [CJ]

pomalidomide 4 mg capsule, 14

12661J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	2535.44	Pomalidomide Sandoz [SZ] Pomolide [JU]	Pomalyst [CJ]

▪ POMALIDOMIDE

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

Note Patients receiving pomalidomide under the PBS listing must be registered in the risk management program relevant for the brand of pomalidomide being prescribed and dispensed: Pomolide - Juno's Pregnancy Prevention Program; Pomalyst - i-access program; Pomalidomide Sandoz - Pregnancy Prevention Program.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment - dual therapy in combination with dexamethasone

Clinical criteria:

- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant, **AND**
- Patient must have experienced treatment failure with lenalidomide, unless contraindicated or not tolerated according to the Therapeutic Goods Administration (TGA) approved Product Information, **AND**
- Patient must have experienced treatment failure with bortezomib, unless contraindicated or not tolerated according to the Therapeutic Goods Administration (TGA) approved Product Information.

Bortezomib treatment failure is the absence of achieving at least a partial response or as progressive disease during treatment or within 6 months of discontinuing treatment with bortezomib. Lenalidomide treatment failure is progressive disease during treatment or within 6 months of discontinuing treatment with lenalidomide.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(1) details (date, unique identifying number/code or provider number) of the reports demonstrating the patient has failed treatment with lenalidomide, including the dates of treatment or the details of the contraindication to or details of the nature and severity of the intolerance to lenalidomide according to the relevant TGA-approved Product Information; and

(2) details (date, unique identifying number/code or provider number) of the reports demonstrating the patient has failed treatment with bortezomib, including the dates of treatment or the details of the contraindication to or details of the nature and severity of the intolerance to bortezomib according to the relevant TGA-approved Product Information.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) 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).

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 authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can 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

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment - dual therapy in combination with dexamethasone

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 PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

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).

pomalidomide 3 mg capsule, 21

10417G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	2846.40	Pomalidomide Sandoz [SZ] Pomolide [JU]	Pomalyst [CJ]

pomalidomide 4 mg capsule, 21

10386P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	3779.25	Pomalidomide Sandoz [SZ] Pomolide [JU]	Pomalyst [CJ]

▪ ROMIPLOSTIM

Authority required

Severe thrombocytopenia

Treatment Phase: Initial treatment - New patient

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4 weeks, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The following criteria indicate failure to achieve an adequate response to corticosteroid and/or immunoglobulin therapy and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The medical practitioner should request 1 vial of the appropriate strength, to titrate therapy based on the weight of the patient. A maximum of 5 repeats will be authorised.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment, may be requested under the Balance of supply or change of therapy restriction. The total period of treatment authorised under this restriction must not exceed 24 weeks.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

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

(1) a completed authority prescription form,

(2) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form, and

(3) details of a platelet count supporting the diagnosis of ITP.

All reports must be documented in the patient's medical records.

The platelet count must be no more than 4 weeks old at the time of application.

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

Authority required

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction if the patient has not had a treatment break, confirmed through a pathology report from an Approved Pathology Authority; OR
- Patient must have swapped treatment from eltrombopag to this drug under the Balance of supply or change of therapy restriction and demonstrated a sustained response; OR
- Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, confirmed through a pathology report from an Approved Pathology Authority, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

For the purposes of this restriction, a sustained response is defined as the patient having the ability to maintain a platelet count sufficient to prevent clinically significant bleeding based on clinical assessment.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug and must be documented in the patient's medical records.

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

Severe thrombocytopenia

Treatment Phase: Second or Subsequent Continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction, **AND**
- Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

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

Severe thrombocytopenia

Treatment Phase: Balance of supply or change of therapy

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment restriction; OR
- Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction; OR
- Patient must have received insufficient therapy with this drug for this condition under the Second or Subsequent Continuing treatment restriction; OR
- Patient must be swapping therapy from eltrombopag to this drug for this condition, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment under this restriction.

Patients receiving treatment with eltrombopag, may change to romiplostim under this restriction.

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).

romiplostim 250 microgram injection, 1 vial

9697J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	521.70	Nplate [AN]

romiplostim 500 microgram injection, 1 vial

9699L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	1035.59	Nplate [AN]

Highly Specialised Drugs Program (Public Hospital)

ELTROMBOPAG

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

Note Special Pricing Arrangements apply.

Authority required

Severe thrombocytopenia

Treatment Phase: Initial treatment - New patient

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4 weeks, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The following criteria indicate failure to achieve an adequate response to corticosteroid and/or immunoglobulin therapy and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

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

(1) a completed authority prescription form,

(2) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form, and

(3) details of a platelet count supporting the diagnosis of ITP.

All reports must be documented in the patient's medical records.

The platelet count must be no more than 4 weeks old at the time of application.

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

Authority required

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction if the patient has not had a treatment break, confirmed through a pathology report from an Approved Pathology Authority; OR
- Patient must have swapped treatment from romiplostim to this drug under the Balance of supply or change of therapy restriction and demonstrated a sustained response; OR
- Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, confirmed through a pathology report from an Approved Pathology Authority, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

For the purposes of this restriction, a sustained response is defined as the patient having the ability to maintain a platelet count sufficient to prevent clinically significant bleeding based on clinical assessment.

The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug and must be documented in the patient's medical records.

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

Severe thrombocytopenia

Treatment Phase: Second or Subsequent Continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction, **AND**
- Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

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

Severe thrombocytopenia

Treatment Phase: Balance of supply or change of therapy

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment restriction; OR
- Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction; OR
- Patient must have received insufficient therapy with this drug for this condition under the Second or Subsequent Continuing treatment restriction; OR
- Patient must be swapping therapy from romiplostim to this drug for this condition, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment under this restriction.

Patients receiving treatment with romiplostim may change to eltrombopag under this restriction.

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).

eltrombopag 25 mg tablet, 28

5825N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	1292.76	Revolade [NV]

eltrombopag 50 mg tablet, 28

5826P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	2585.52	Revolade [NV]

▪ POMALIDOMIDE

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

Note 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).

Note Patients receiving pomalidomide under the PBS listing must be registered in the risk management program relevant for the brand of pomalidomide being prescribed and dispensed: Pomolide - Juno's Pregnancy Prevention Program; Pomalyst - i-access program; Pomalidomide Sandoz - Pregnancy Prevention Program.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment with triple therapy (this drug, bortezomib and dexamethasone)

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy that is either: (i) lenalidomide monotherapy, (ii) contains lenalidomide, **AND**
- Patient must have undergone or be ineligible for a stem cell transplant.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment with triple therapy (this drug, bortezomib and dexamethasone)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

pomalidomide 3 mg capsule, 14

12666P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	1865.72	Pomalidomide Sandoz [SZ] Pomolide [JU]	Pomalyst [CJ]

pomalidomide 4 mg capsule, 14

12665N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	2487.62	Pomalidomide Sandoz [SZ] Pomolide [JU]	Pomalyst [CJ]

▪ POMALIDOMIDE

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

Note Patients receiving pomalidomide under the PBS listing must be registered in the risk management program relevant for the brand of pomalidomide being prescribed and dispensed: Pomolide - Juno's Pregnancy Prevention Program; Pomalyst - i-access program; Pomalidomide Sandoz - Pregnancy Prevention Program.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment - dual therapy in combination with dexamethasone

Clinical criteria:

- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant, **AND**
- Patient must have experienced treatment failure with lenalidomide, unless contraindicated or not tolerated according to the Therapeutic Goods Administration (TGA) approved Product Information, **AND**
- Patient must have experienced treatment failure with bortezomib, unless contraindicated or not tolerated according to the Therapeutic Goods Administration (TGA) approved Product Information.

Bortezomib treatment failure is the absence of achieving at least a partial response or as progressive disease during treatment or within 6 months of discontinuing treatment with bortezomib. Lenalidomide treatment failure is progressive disease during treatment or within 6 months of discontinuing treatment with lenalidomide.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(1) details (date, unique identifying number/code or provider number) of the reports demonstrating the patient has failed treatment with lenalidomide, including the dates of treatment or the details of the contraindication to or details of the nature and severity of the intolerance to lenalidomide according to the relevant TGA-approved Product Information; and

(2) details (date, unique identifying number/code or provider number) of the reports demonstrating the patient has failed treatment with bortezomib, including the dates of treatment or the details of the contraindication to or details of the nature and severity of the intolerance to bortezomib according to the relevant TGA-approved Product Information.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) 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).

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 authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can 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

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment - dual therapy in combination with dexamethasone

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 PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

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).

pomalidomide 3 mg capsule, 21

10406Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	2798.58	Pomalidomide Sandoz [SZ] Pomolide [JU]	Pomalyst [CJ]

pomalidomide 4 mg capsule, 21

10387Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	3731.43	Pomalidomide Sandoz [SZ] Pomolide [JU]	Pomalyst [CJ]

▪ ROMIPLOSTIM

Authority required

Severe thrombocytopenia

Treatment Phase: Initial treatment - New patient

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4 weeks, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The following criteria indicate failure to achieve an adequate response to corticosteroid and/or immunoglobulin therapy and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The medical practitioner should request 1 vial of the appropriate strength, to titrate therapy based on the weight of the patient. A maximum of 5 repeats will be authorised.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment, may be requested under the Balance of supply or change of therapy restriction. The total period of treatment authorised under this restriction must not exceed 24 weeks.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

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

(1) a completed authority prescription form,

(2) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form, and

(3) details of a platelet count supporting the diagnosis of ITP.

All reports must be documented in the patient's medical records.

The platelet count must be no more than 4 weeks old at the time of application.

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

Authority required

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction if the patient has not had a treatment break, confirmed through a pathology report from an Approved Pathology Authority; OR
- Patient must have swapped treatment from eltrombopag to this drug under the Balance of supply or change of therapy restriction and demonstrated a sustained response; OR
- Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, confirmed through a pathology report from an Approved Pathology Authority, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

For the purposes of this restriction, a sustained response is defined as the patient having the ability to maintain a platelet count sufficient to prevent clinically significant bleeding based on clinical assessment.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug and must be documented in the patient's medical records.

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

Severe thrombocytopenia

Treatment Phase: Second or Subsequent Continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction, **AND**
- Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

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

Severe thrombocytopenia

Treatment Phase: Balance of supply or change of therapy

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment restriction; OR
- Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction; OR
- Patient must have received insufficient therapy with this drug for this condition under the Second or Subsequent Continuing treatment restriction; OR
- Patient must be swapping therapy from eltrombopag to this drug for this condition, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment under this restriction.

Patients receiving treatment with eltrombopag, may change to romiplostim under this restriction.

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).

romiplostim 250 microgram injection, 1 vial

9696H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	494.12	Nplate [AN]

romiplostim 500 microgram injection, 1 vial

9698K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	988.24	Nplate [AN]