Australian Government

Department of Health, Disability and Ageing

PBS

Schedule of Pharmaceutical Benefits

Summary of Changes

Effective 1 August 2026

Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 August 2026 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	$9.24
	Dangerous drug fee	$5.73
	Extemporaneously-prepared	$11.28
	Allowable additional patient charge*	$2.79
Additional Fees (for safety net prices):	Ready-prepared	$1.54
	Extemporaneously-prepared	$1.99
Patient Co-payments:	General	$25.00
	Concessional	$7.70
Safety Net Thresholds:	General	$1748.20
	Concessional	$277.20
Safety Net Card Issue Fee:		$12.78

* 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 August 2026. The Schedule is updated on the first day of each month and is also available at www.pbs.gov.au.

Prescriber Bag

Additions

Addition – Brand

3486L *PEN G Sandoz, HX* – **BENZYLPENICILLIN**, benzylpenicillin 600 mg injection, 1 vial

Addition – Equivalence Indicator

3486L *BenPen, SZ* – **BENZYLPENICILLIN**, benzylpenicillin 600 mg injection, 1 vial

General Pharmaceutical Benefits

Additions

Addition – Item

15436K **ABALOPARATIDE**, Abaloparatide 2 mg/mL injection, 1.5 mL pen device *(Eladynos)*

15468D **ABALOPARATIDE**, Abaloparatide 2 mg/mL injection, 1.5 mL pen device *(Eladynos)*

15423R **OXYCODONE**, oxycodone hydrochloride 5 mg capsule, 20 *(Oxycodone BNM, OxyNorm)*

15424T **OXYCODONE**, oxycodone hydrochloride 5 mg tablet, 20 *(ENDONE, Mayne Pharma Oxycodone IR, Oxycodone Viatris, Oxyndone)*

15450E **OXYCODONE**, oxycodone hydrochloride 5 mg tablet, 20 *(ENDONE, Mayne Pharma Oxycodone IR, Oxycodone Viatris, Oxyndone)*

15495M **OXYCODONE**, oxycodone hydrochloride 5 mg capsule, 20 *(Oxycodone BNM, OxyNorm)*

15447B **SELPERCATINIB**, Selpercatinib 40 mg tablet, 56 *(Retevmo)*

15494L **SELPERCATINIB**, Selpercatinib 80 mg tablet, 56 *(Retevmo)*

15448C **TILDRAKIZUMAB**, Tildrakizumab 100 mg/mL injection, 2 x 1 mL syringes *(Ilumya)*

15449D **TILDRAKIZUMAB**, Tildrakizumab 100 mg/mL injection, 2 x 1 mL syringes *(Ilumya)*

15458N **TILDRAKIZUMAB**, Tildrakizumab 100 mg/mL injection, 2 x 1 mL syringes *(Ilumya)*

15437L **VORASIDENIB**, Vorasidenib 10 mg tablet, 30 *(Voranigo)*

15461R **VORASIDENIB**, Vorasidenib 40 mg tablet, 30 *(Voranigo)*

Addition – Brand

5500L *Apexa, CR* – **APIXABAN**, apixaban 2.5 mg tablet, 20

5500L *Apixaban-APX, XW* – **APIXABAN**, apixaban 2.5 mg tablet, 20

5500L *Cip Apixaban 2.5, LR* – **APIXABAN**, apixaban 2.5 mg tablet, 20

5054B *Apexa, CR* – **APIXABAN**, apixaban 2.5 mg tablet, 30

5054B *Cip Apixaban 2.5, LR* – **APIXABAN**, apixaban 2.5 mg tablet, 30

2744K *Apexa, CR* – **APIXABAN**, apixaban 2.5 mg tablet, 60

5061J *Apexa, CR* – **APIXABAN**, apixaban 2.5 mg tablet, 60

13464P *Apexa, CR* – **APIXABAN**, apixaban 2.5 mg tablet, 60

2744K *Apixaban-APX, XW* – **APIXABAN**, apixaban 2.5 mg tablet, 60

5061J *Apixaban-APX, XW* – **APIXABAN**, apixaban 2.5 mg tablet, 60

13464P *Apixaban-APX, XW* – **APIXABAN**, apixaban 2.5 mg tablet, 60

2744K *Apixaban Lupin, GQ* – **APIXABAN**, apixaban 2.5 mg tablet, 60

5061J *Apixaban Lupin, GQ* – **APIXABAN**, apixaban 2.5 mg tablet, 60

13464P *Apixaban Lupin, GQ* – **APIXABAN**, apixaban 2.5 mg tablet, 60

2744K *Apixaban Sandoz, SZ* – **APIXABAN**, apixaban 2.5 mg tablet, 60

5061J *Apixaban Sandoz, SZ* – **APIXABAN**, apixaban 2.5 mg tablet, 60

13464P *Apixaban Sandoz, SZ* – **APIXABAN**, apixaban 2.5 mg tablet, 60

2744K *APIXABAN-WGR, WG* – **APIXABAN**, apixaban 2.5 mg tablet, 60

5061J *APIXABAN-WGR, WG* – **APIXABAN**, apixaban 2.5 mg tablet, 60

13464P *APIXABAN-WGR, WG* – **APIXABAN**, apixaban 2.5 mg tablet, 60

2744K *APO-Apixaban, TX* – **APIXABAN**, apixaban 2.5 mg tablet, 60

5061J *APO-Apixaban, TX* – **APIXABAN**, apixaban 2.5 mg tablet, 60

13464P *APO-Apixaban, TX* – **APIXABAN**, apixaban 2.5 mg tablet, 60

2744K *Cip Apixaban 2.5, LR* – **APIXABAN**, apixaban 2.5 mg tablet, 60

5061J *Cip Apixaban 2.5, LR* – **APIXABAN**, apixaban 2.5 mg tablet, 60

13464P *Cip Apixaban 2.5, LR* – **APIXABAN**, apixaban 2.5 mg tablet, 60

2735Y *Apexa, CR* – **APIXABAN**, apixaban 5 mg tablet, 60

13525W *Apexa, CR* – **APIXABAN**, apixaban 5 mg tablet, 60

2735Y *Apixaban-APX, XW* – **APIXABAN**, apixaban 5 mg tablet, 60

13525W *Apixaban-APX, XW* – **APIXABAN**, apixaban 5 mg tablet, 60

2735Y *Apixaban Lupin, GQ* – **APIXABAN**, apixaban 5 mg tablet, 60

13525W *Apixaban Lupin, GQ* – **APIXABAN**, apixaban 5 mg tablet, 60

2735Y *Apixaban Sandoz, SZ* – **APIXABAN**, apixaban 5 mg tablet, 60

13525W *Apixaban Sandoz, SZ* – **APIXABAN**, apixaban 5 mg tablet, 60

2735Y *APIXABAN-WGR, WG* – **APIXABAN**, apixaban 5 mg tablet, 60

13525W *APIXABAN-WGR, WG* – **APIXABAN**, apixaban 5 mg tablet, 60

2735Y *APO-Apixaban, TX* – **APIXABAN**, apixaban 5 mg tablet, 60

13525W *APO-Apixaban, TX* – **APIXABAN**, apixaban 5 mg tablet, 60

2735Y *Cip Apixaban 5, LR* – **APIXABAN**, apixaban 5 mg tablet, 60

13525W *Cip Apixaban 5, LR* – **APIXABAN**, apixaban 5 mg tablet, 60

1775K *PEN G Sandoz, HX* – **BENZYLPENICILLIN**, benzylpenicillin 600 mg injection, 1 vial

3398W *PEN G Sandoz, HX* – **BENZYLPENICILLIN**, benzylpenicillin 600 mg injection, 1 vial

10104T *FERRICARBO, RZ* – **FERRIC CARBOXYMALTOSE**, iron (as ferric carboxymaltose) 500 mg/10 mL injection, 10 mL vial

11702X *FERRICARBO, RZ* – **FERRIC CARBOXYMALTOSE**, iron (as ferric carboxymaltose) 1 g/20 mL injection, 20 mL vial

8740B *CALCIUM FOLINATE MEDSURGE, DZ* – **FOLINIC ACID**, folinic acid 50 mg/5 mL injection, 5 mL vial

11452R *Guanfacine Sandoz, SZ* – **GUANFACINE**, guanfacine 1 mg modified release tablet, 28

11452R *Guanfacine Viatris, AF* – **GUANFACINE**, guanfacine 1 mg modified release tablet, 28

11451Q *Guanfacine Sandoz, SZ* – **GUANFACINE**, guanfacine 2 mg modified release tablet, 28

11451Q *Guanfacine Viatris, AF* – **GUANFACINE**, guanfacine 2 mg modified release tablet, 28

11440D *Guanfacine Sandoz, SZ* – **GUANFACINE**, guanfacine 3 mg modified release tablet, 28

11440D *Guanfacine Viatris, AF* – **GUANFACINE**, guanfacine 3 mg modified release tablet, 28

11441E *Guanfacine Sandoz, SZ* – **GUANFACINE**, guanfacine 4 mg modified release tablet, 28

11441E *Guanfacine Viatris, AF* – **GUANFACINE**, guanfacine 4 mg modified release tablet, 28

2868Y *GLENMECT, JM* – **IVERMECTIN**, ivermectin 3 mg tablet, 4

8359Y *GLENMECT, JM* – **IVERMECTIN**, ivermectin 3 mg tablet, 4

2913H *Mirolesa, LJ* – **LEVONORGESTREL**, levonorgestrel 30 microgram tablet, 112 tablets [4 x 28]

3124K *Uraleev, NB* – **METHENAMINE HIPPURATE**, methenamine hippurate 1 g tablet, 100

14005D *Uraleev, NB* – **METHENAMINE HIPPURATE**, methenamine hippurate 1 g tablet, 100

5472B *Ondansetron ODT VTRS, MQ* – **ONDANSETRON**, ondansetron 4 mg orally disintegrating tablet, 10

1594X *Ondansetron VTRS, AF* – **ONDANSETRON**, ondansetron 4 mg tablet, 10

5471Y *Ondansetron ODT VTRS, MQ* – **ONDANSETRON**, ondansetron 8 mg orally disintegrating tablet, 4

14730G *PROGESTERONE-APX, XT* – **PROGESTERONE**, progesterone 100 mg capsule, 30

14733K *PROGESTERONE-APX, XT* – **PROGESTERONE**, progesterone 100 mg capsule, 30

9467G *TROXA, XG* – **RIVAROXABAN**, rivaroxaban 10 mg tablet, 30

11633G *TROXA, XG* – **RIVAROXABAN**, rivaroxaban 10 mg tablet, 30

13521P *TROXA, XG* – **RIVAROXABAN**, rivaroxaban 10 mg tablet, 30

2691P *TROXA, XG* – **RIVAROXABAN**, rivaroxaban 15 mg tablet, 28

13463N *TROXA, XG* – **RIVAROXABAN**, rivaroxaban 15 mg tablet, 28

2268J *TROXA, XG* – **RIVAROXABAN**, rivaroxaban 20 mg tablet, 28

13462M *TROXA, XG* – **RIVAROXABAN**, rivaroxaban 20 mg tablet, 28

1418P *Ticagrelor Sandoz, SZ* – **TICAGRELOR**, ticagrelor 90 mg tablet, 56

13524T *Ticagrelor Sandoz, SZ* – **TICAGRELOR**, ticagrelor 90 mg tablet, 56

Addition – Equivalence Indicator

5500L *Eliquis, XT* – **APIXABAN**, apixaban 2.5 mg tablet, 20

5054B *Eliquis, XT* – **APIXABAN**, apixaban 2.5 mg tablet, 30

2744K *Eliquis, XT* – **APIXABAN**, apixaban 2.5 mg tablet, 60

5061J *Eliquis, XT* – **APIXABAN**, apixaban 2.5 mg tablet, 60

13464P *Eliquis, XT* – **APIXABAN**, apixaban 2.5 mg tablet, 60

2735Y *Eliquis, XT* – **APIXABAN**, apixaban 5 mg tablet, 60

13525W *Eliquis, XT* – **APIXABAN**, apixaban 5 mg tablet, 60

1775K *BenPen, SZ* – **BENZYLPENICILLIN**, benzylpenicillin 600 mg injection, 1 vial

3398W *BenPen, SZ* – **BENZYLPENICILLIN**, benzylpenicillin 600 mg injection, 1 vial

11452R *Intuniv, TK* – **GUANFACINE**, guanfacine 1 mg modified release tablet, 28

11451Q *Intuniv, TK* – **GUANFACINE**, guanfacine 2 mg modified release tablet, 28

11440D *Intuniv, TK* – **GUANFACINE**, guanfacine 3 mg modified release tablet, 28

11441E *Intuniv, TK* – **GUANFACINE**, guanfacine 4 mg modified release tablet, 28

2868Y *Stromectol, MK* – **IVERMECTIN**, ivermectin 3 mg tablet, 4

8359Y *Stromectol, MK* – **IVERMECTIN**, ivermectin 3 mg tablet, 4

2913H *Microlut 28, XW* – **LEVONORGESTREL**, levonorgestrel 30 microgram tablet, 112 tablets [4 x 28]

Addition – Note

12311Y **OXYCODONE**, oxycodone hydrochloride 5 mg capsule, 10 *(OxyNorm)*

12314D **OXYCODONE**, oxycodone hydrochloride 5 mg capsule, 10 *(OxyNorm)*

13233L **OXYCODONE**, oxycodone hydrochloride 5 mg tablet, 10 *(ENDONE, Oxycodone Viatris)*

13234M **OXYCODONE**, oxycodone hydrochloride 5 mg tablet, 10 *(ENDONE, Oxycodone Viatris)*

1975Y **QUININE**, quinine sulfate dihydrate 300 mg tablet, 50 *(Quinate)*

Deletions

Deletion – Item

15076L **CLOPIDOGREL**, clopidogrel 75 mg tablet, 30 *(Clopidogrel Tablets, USP 75 mg (Novadoz, USA))*

15081R **CLOPIDOGREL**, clopidogrel 75 mg tablet, 30 *(Clopidogrel Tablets, USP 75 mg (Aurobindo, USA))*

15085Y **CLOPIDOGREL**, clopidogrel 75 mg tablet, 30 *(Clopidogrel Tablets, USP 75 mg (Aurobindo, USA))*

15086B **CLOPIDOGREL**, clopidogrel 75 mg tablet, 30 *(Clopidogrel Tablets, USP 75 mg (Novadoz, USA))*

1610R **FOLINIC ACID**, folinic acid 50 mg/5 mL injection, 10 x 5 mL ampoules *(Leucovorin Calcium (Pfizer Australia Pty Ltd))*

8084L **INSULIN LISPRO**, insulin lispro 100 units/mL injection, 1 x 10 mL vial *(Humalog)*

1426C **INSULIN NEUTRAL HUMAN + INSULIN ISOPHANE HUMAN**, insulin neutral human 30 units/mL + insulin isophane human 70 units/mL injection, 10 mL vial *(Humulin 30/70)*

15109F **METHYLPHENIDATE**, methylphenidate hydrochloride 10 mg modified release capsule, 30 *(Ritalin LA 10 mg (Switzerland))*

15101T **METHYLPHENIDATE**, methylphenidate hydrochloride 20 mg modified release capsule, 30 *(Ritalin LA 20 mg (Switzerland))*

15070E **METHYLPHENIDATE**, methylphenidate hydrochloride 30 mg modified release capsule, 100 *(Ritalin LA 30 mg (Switzerland))*

15099Q **METHYLPHENIDATE**, methylphenidate hydrochloride 30 mg modified release capsule, 30 *(Ritalin LA 30 mg (Switzerland))*

15100R **METHYLPHENIDATE**, methylphenidate hydrochloride 40 mg modified release capsule, 30 *(Ritalin LA 40 mg (Switzerland))*

Deletion – Brand

3094W *Keflex, AS* – **CEFALEXIN**, cefalexin 125 mg/5 mL powder for oral liquid, 100 mL

3319Q *Keflex, AS* – **CEFALEXIN**, cefalexin 125 mg/5 mL powder for oral liquid, 100 mL

1533Q *Humulin NPH, LY* – **INSULIN ISOPHANE HUMAN**, insulin isophane human 100 units/mL injection, 1 x 10 mL vial

1531N *Humulin R, LY* – **INSULIN NEUTRAL HUMAN**, insulin neutral human 100 units/mL injection, 1 x 10 mL vial

1928L *Depo-Nisolone, FZ* – **METHYLPREDNISOLONE**, methylprednisolone acetate 40 mg/mL modified release injection, 5 x 1 mL vials

5148Y *Depo-Nisolone, FZ* – **METHYLPREDNISOLONE**, methylprednisolone acetate 40 mg/mL modified release injection, 5 x 1 mL vials

3382B *OLANZAPINE ODT-WGR, WG* – **OLANZAPINE**, olanzapine 10 mg orally disintegrating tablet, 28

1944H *Ramipril Winthrop, WA* – **RAMIPRIL**, ramipril 1.25 mg tablet, 30

13582W *Ramipril Winthrop, WA* – **RAMIPRIL**, ramipril 1.25 mg tablet, 30

8380C *Temodal, MK* – **TEMOZOLOMIDE**, temozolomide 100 mg capsule, 5

8821G *Temodal, MK* – **TEMOZOLOMIDE**, temozolomide 100 mg capsule, 5

9361Q *Temodal, MK* – **TEMOZOLOMIDE**, temozolomide 140 mg capsule, 5

9362R *Temodal, MK* – **TEMOZOLOMIDE**, temozolomide 140 mg capsule, 5

Deletion – Equivalence Indicator

1928L *Depo-Medrol, PF* – **METHYLPREDNISOLONE**, methylprednisolone acetate 40 mg/mL modified release injection, 5 x 1 mL vials

5148Y *Depo-Medrol, PF* – **METHYLPREDNISOLONE**, methylprednisolone acetate 40 mg/mL modified release injection, 5 x 1 mL vials

Deletion – Note

8740B **FOLINIC ACID**, folinic acid 50 mg/5 mL injection, 5 mL vial *(CALCIUM FOLINATE MEDSURGE, DBL Leucovorin Calcium)*

11452R **GUANFACINE**, guanfacine 1 mg modified release tablet, 28 *(Guanfacine Sandoz, Guanfacine Viatris, Intuniv)*

11451Q **GUANFACINE**, guanfacine 2 mg modified release tablet, 28 *(Guanfacine Sandoz, Guanfacine Viatris, Intuniv)*

11440D **GUANFACINE**, guanfacine 3 mg modified release tablet, 28 *(Guanfacine Sandoz, Guanfacine Viatris, Intuniv)*

11441E **GUANFACINE**, guanfacine 4 mg modified release tablet, 28 *(Guanfacine Sandoz, Guanfacine Viatris, Intuniv)*

3440C **METHYLPHENIDATE**, methylphenidate hydrochloride 10 mg modified release capsule, 30 *(ATTORA LA, Ritalin LA, Rubifen LA)*

2276T **METHYLPHENIDATE**, methylphenidate hydrochloride 20 mg modified release capsule, 30 *(ATTORA LA, Ritalin LA, Rubifen LA)*

2280B **METHYLPHENIDATE**, methylphenidate hydrochloride 30 mg modified release capsule, 30 *(ATTORA LA, Ritalin LA, Rubifen LA)*

2283E **METHYLPHENIDATE**, methylphenidate hydrochloride 40 mg modified release capsule, 30 *(ATTORA LA, Ritalin LA, Rubifen LA)*

Alterations

Alteration – Note

12407B **ADALIMUMAB**, adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes *(Humira)*

12423W **ADALIMUMAB**, adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes *(Humira)*

14995F **ADALIMUMAB**, adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes *(Humira)*

12332C **ADALIMUMAB**, adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe *(Amgevita)*

12354F **ADALIMUMAB**, adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe *(Amgevita)*

12436M **ADALIMUMAB**, adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe *(Amgevita)*

12338J **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes *(Hadlima, Humira, Hyrimoz, Yuflyma)*

12373F **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices *(Hadlima, Humira, Hyrimoz, Yuflyma)*

12379M **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes *(Hadlima, Humira, Hyrimoz, Yuflyma)*

12411F **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices *(Hadlima, Humira, Hyrimoz, Yuflyma)*

12432H **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices *(Hadlima, Humira, Hyrimoz, Yuflyma)*

12455M **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes *(Hadlima, Humira, Hyrimoz, Yuflyma)*

13218Q **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes *(Hadlima, Humira, Hyrimoz, Yuflyma)*

13224B **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices *(Hadlima, Humira, Hyrimoz, Yuflyma)*

10399H **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes *(Amgevita, Hadlima, Hyrimoz)*

10400J **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices *(Abrilada, Amgevita, Hadlima, Hyrimoz)*

10413C **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices *(Abrilada, Amgevita, Hadlima, Hyrimoz)*

10419J **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes *(Amgevita, Hadlima, Hyrimoz)*

12388B **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices *(Abrilada, Amgevita, Hadlima, Hyrimoz)*

12416L **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes *(Amgevita, Hadlima, Hyrimoz)*

12420Q **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices *(Abrilada, Amgevita, Hadlima, Hyrimoz)*

12434K **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes *(Amgevita, Hadlima, Hyrimoz)*

12409D **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe *(Humira, Yuflyma)*

12426B **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device *(Humira, Hyrimoz, Yuflyma)*

8358X **CLOPIDOGREL**, clopidogrel 75 mg tablet, 28 *(Blooms Clopidogrel, Clopidogrel Lupin, Clopidogrel Sandoz Pharma, Clopidogrel Winthrop, Iscover, Piax, Plavicor 75)*

9354H **CLOPIDOGREL**, clopidogrel 75 mg tablet, 28 *(CLOPIDOGREL-WGR, Clovix 75, Plidogrel)*

13365K **CLOPIDOGREL**, clopidogrel 75 mg tablet, 28 *(CLOPIDOGREL-WGR, Clovix 75, Plidogrel)*

13399F **CLOPIDOGREL**, clopidogrel 75 mg tablet, 28 *(Blooms Clopidogrel, Clopidogrel Lupin, Clopidogrel Sandoz Pharma, Clopidogrel Winthrop, Iscover, Piax, Plavicor 75)*

Alteration – Restriction

12407B **ADALIMUMAB**, adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes *(Humira)*

12423W **ADALIMUMAB**, adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes *(Humira)*

14995F **ADALIMUMAB**, adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes *(Humira)*

12332C **ADALIMUMAB**, adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe *(Amgevita)*

12354F **ADALIMUMAB**, adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe *(Amgevita)*

12436M **ADALIMUMAB**, adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe *(Amgevita)*

12338J **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes *(Hadlima, Humira, Hyrimoz, Yuflyma)*

12373F **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices *(Hadlima, Humira, Hyrimoz, Yuflyma)*

12379M **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes *(Hadlima, Humira, Hyrimoz, Yuflyma)*

12411F **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices *(Hadlima, Humira, Hyrimoz, Yuflyma)*

12432H **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices *(Hadlima, Humira, Hyrimoz, Yuflyma)*

12455M **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes *(Hadlima, Humira, Hyrimoz, Yuflyma)*

13218Q **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes *(Hadlima, Humira, Hyrimoz, Yuflyma)*

13224B **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices *(Hadlima, Humira, Hyrimoz, Yuflyma)*

10399H **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes *(Amgevita, Hadlima, Hyrimoz)*

10400J **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices *(Abrilada, Amgevita, Hadlima, Hyrimoz)*

10413C **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices *(Abrilada, Amgevita, Hadlima, Hyrimoz)*

10419J **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes *(Amgevita, Hadlima, Hyrimoz)*

12388B **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices *(Abrilada, Amgevita, Hadlima, Hyrimoz)*

12416L **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes *(Amgevita, Hadlima, Hyrimoz)*

12420Q **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices *(Abrilada, Amgevita, Hadlima, Hyrimoz)*

12434K **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes *(Amgevita, Hadlima, Hyrimoz)*

12409D **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe *(Humira, Yuflyma)*

12426B **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device *(Humira, Hyrimoz, Yuflyma)*

14792M **EPCORITAMAB**, Epcoritamab 4 mg/0.8 mL injection, 0.8 mL vial *(Epkinly)*

12551N **INFLIXIMAB**, infliximab 120 mg/mL injection, 1 mL pen device *(Remsima SC)*

12585J **INFLIXIMAB**, infliximab 120 mg/mL injection, 1 mL syringe *(Remsima SC)*

14573B **MIGALASTAT**, migalastat 123 mg capsule, 14 *(Galafold)*

1975Y **QUININE**, quinine sulfate dihydrate 300 mg tablet, 50 *(Quinate)*

12301K **ROMOSOZUMAB**, romosozumab 105 mg/1.17 mL injection, 2 x 1.17 mL syringes *(Evenity)*

14641N **ROMOSOZUMAB**, romosozumab 105 mg/1.17 mL injection, 2 x 1.17 mL syringes *(Evenity)*

14093R **TERIPARATIDE**, teriparatide 250 microgram/mL injection, 2.4 mL pen device *(Teriparatide Lupin, Terrosa)*

15152L **TERIPARATIDE**, teriparatide 250 microgram/mL injection, 2.4 mL cartridge *(Ritosa)*

Alteration – Restriction Level

		From	*To*
1975Y	**QUININE** quinine sulfate dihydrate 300 mg tablet, 50 *(Quinate)*	streamlined	authority-required

Alteration – Manufacturer Code

		From	*To*
15359J	*Jext Jnr* – **ADRENALINE (EPINEPHRINE)**, adrenaline (epinephrine) 150 microgram/0.15 mL injection, 0.15 mL pen device	KB	KF
15355E	*Jext* – **ADRENALINE (EPINEPHRINE)**, adrenaline (epinephrine) 300 microgram/0.3 mL injection, 0.3 mL pen device	KB	KF
5500L	*Eliquis* – **APIXABAN**, apixaban 2.5 mg tablet, 20	BQ	XT
5054B	*Eliquis* – **APIXABAN**, apixaban 2.5 mg tablet, 30	BQ	XT
2744K	*Eliquis* – **APIXABAN**, apixaban 2.5 mg tablet, 60	BQ	XT
5061J	*Eliquis* – **APIXABAN**, apixaban 2.5 mg tablet, 60	BQ	XT
13464P	*Eliquis* – **APIXABAN**, apixaban 2.5 mg tablet, 60	BQ	XT
2735Y	*Eliquis* – **APIXABAN**, apixaban 5 mg tablet, 60	BQ	XT
13525W	*Eliquis* – **APIXABAN**, apixaban 5 mg tablet, 60	BQ	XT
1418P	*TICALOR* – **TICAGRELOR**, ticagrelor 90 mg tablet, 56	XE	BZ
13524T	*TICALOR* – **TICAGRELOR**, ticagrelor 90 mg tablet, 56	XE	BZ

Supply Only

Supply Only – Period Commencing

12424X **ADALIMUMAB**, adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes *(Humira)*

12440R **ADALIMUMAB**, adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe *(Amgevita)*

12341M **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices *(Hadlima, Humira, Hyrimoz, Yuflyma)*

12413H **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes *(Hadlima, Humira, Hyrimoz, Yuflyma)*

10412B **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes *(Amgevita, Hadlima, Hyrimoz)*

10420K **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices *(Abrilada, Amgevita, Hadlima, Hyrimoz)*

8409N **BECLOMETASONE**, beclometasone dipropionate 100 microgram/actuation breath activated inhalation, 200 actuations *(Qvar 100 Autohaler)*

14514X **BECLOMETASONE**, beclometasone dipropionate 100 microgram/actuation breath activated inhalation, 200 actuations *(Qvar 100 Autohaler)*

8027L **GLYCERYL TRINITRATE**, glyceryl trinitrate 5 mg/24 hours patch, 30 *(Minitran 5)*

14371J **GLYCERYL TRINITRATE**, glyceryl trinitrate 5 mg/24 hours patch, 30 *(Minitran 5)*

9031H **MICONAZOLE**, miconazole 2% solution, 30 mL *(Daktarin Tincture)*

Advance Notices

1 September 2026

Deletion – Item

1750D *Poly Visc, IQ* – **PARAFFIN**, paraffin 1 g/g eye ointment, 2 x 3.5 g

5522P *Poly Visc, IQ* – **PARAFFIN**, paraffin 1 g/g eye ointment, 2 x 3.5 g

14493T *Poly Visc, IQ* – **PARAFFIN**, paraffin 1 g/g eye ointment, 2 x 3.5 g

Deletion – Brand

1884E *Amoxil, AS* – **AMOXICILLIN**, amoxicillin 250 mg capsule, 20

3301R *Amoxil, AS* – **AMOXICILLIN**, amoxicillin 250 mg capsule, 20

11998L *Amoxil, AS* – **AMOXICILLIN**, amoxicillin 250 mg capsule, 20

8719X *ARIPIPRAZOLE-WGR, WG* – **ARIPIPRAZOLE**, aripiprazole 20 mg tablet, 30

8480H *Cardizem CD, SW* – **DILTIAZEM**, diltiazem hydrochloride 360 mg modified release capsule, 30

14565N *Cardizem CD, SW* – **DILTIAZEM**, diltiazem hydrochloride 360 mg modified release capsule, 30

8533D *GLIMEPIRIDE-WGR, WG* – **GLIMEPIRIDE**, glimepiride 3 mg tablet, 30

14020X *GLIMEPIRIDE-WGR, WG* – **GLIMEPIRIDE**, glimepiride 3 mg tablet, 30

3385E *OLANZAPINE ODT-WGR, WG* – **OLANZAPINE**, olanzapine 20 mg orally disintegrating tablet, 28

8695P *Actos, GQ* – **PIOGLITAZONE**, pioglitazone 30 mg tablet, 28

13921Q *Actos, GQ* – **PIOGLITAZONE**, pioglitazone 30 mg tablet, 28

1 October 2026

Deletion – Brand

2604C *NOUMED ALLOPURINOL, VO* – **ALLOPURINOL**, allopurinol 300 mg tablet, 60

13575L *NOUMED ALLOPURINOL, VO* – **ALLOPURINOL**, allopurinol 300 mg tablet, 60

8655M *Levetiracetam Mylan, AL* – **LEVETIRACETAM**, levetiracetam 500 mg tablet, 60

14034P *Levetiracetam Mylan, AL* – **LEVETIRACETAM**, levetiracetam 500 mg tablet, 60

1 November 2026

Deletion – Item

13110B *Copaxone, TB* – **GLATIRAMER ACETATE**, glatiramer acetate 40 mg/mL injection, 12 x 1 mL pen devices

Deletion – Brand

8720Y *ARIPIPRAZOLE-WGR, WG* – **ARIPIPRAZOLE**, aripiprazole 30 mg tablet, 30

9344T *Lecteva, TB* – **LEVODOPA + CARBIDOPA + ENTACAPONE**, levodopa 75 mg + carbidopa 18.75 mg + entacapone 200 mg tablet, 100

14498C *Lecteva, TB* – **LEVODOPA + CARBIDOPA + ENTACAPONE**, levodopa 75 mg + carbidopa 18.75 mg + entacapone 200 mg tablet, 100

3381Y *OLANZAPINE ODT-WGR, WG* – **OLANZAPINE**, olanzapine 5 mg orally disintegrating tablet, 28

3384D *OLANZAPINE ODT-WGR, WG* – **OLANZAPINE**, olanzapine 15 mg orally disintegrating tablet, 28

Highly Specialised Drugs Program (Private Hospital)

Additions

Addition – Item

15479Q **BUROSUMAB**, burosumab 10 mg/mL injection, 1 mL vial *(Crysvita)*

15500T **BUROSUMAB**, burosumab 20 mg/mL injection, 1 mL vial *(Crysvita)*

15493K **BUROSUMAB**, burosumab 30 mg/mL injection, 1 mL vial *(Crysvita)*

15418L **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

15485B **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

15488E **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

15486C **LENALIDOMIDE**, lenalidomide 20 mg capsule, 21 *(Lenalide, Lenalidomide Sandoz)*

15481T **NITISINONE**, nitisinone 2 mg capsule, 60 *(Orfadin)*

15502X **NITISINONE**, nitisinone 4 mg/mL oral liquid, 90 mL *(Orfadin)*

15425W **NITISINONE**, nitisinone 5 mg capsule, 60 *(Orfadin)*

15467C **NITISINONE**, nitisinone 10 mg capsule, 60 *(Orfadin)*

15459P **NITISINONE**, nitisinone 20 mg capsule, 60 *(Orfadin)*

15483X **PEGUNIGALSIDASE ALFA**, Pegunigalsidase alfa 20 mg/10 mL injection, 10 mL vial *(ELFABRIO)*

Addition – Brand

11450P *Remicade, JC* – **INFLIXIMAB**, infliximab 100 mg injection, 1 vial

Deletions

Deletion – Item

14296K **PATISIRAN**, patisiran 10 mg/5 mL injection, 5 mL vial *(Onpattro)*

Deletion – Brand

9648T *Cipla Ambrisentan, ZU* – **AMBRISENTAN**, ambrisentan 5 mg tablet, 30

12201E *Cipla Ambrisentan, ZU* – **AMBRISENTAN**, ambrisentan 5 mg tablet, 30

6499C *Pharmacor Deferasirox, CR* – **DEFERASIROX**, deferasirox 125 mg dispersible tablet, 28

11236J *Pharmacor Deferasirox, CR* – **DEFERASIROX**, deferasirox 125 mg dispersible tablet, 28

11241P *Pharmacor Deferasirox, CR* – **DEFERASIROX**, deferasirox 125 mg dispersible tablet, 28

6500D *Pharmacor Deferasirox, CR* – **DEFERASIROX**, deferasirox 250 mg dispersible tablet, 28

11238L *Pharmacor Deferasirox, CR* – **DEFERASIROX**, deferasirox 250 mg dispersible tablet, 28

11244T *Pharmacor Deferasirox, CR* – **DEFERASIROX**, deferasirox 250 mg dispersible tablet, 28

Deletion – Equivalence Indicator

6499C *Deferasirox Juno, JU* – **DEFERASIROX**, deferasirox 125 mg dispersible tablet, 28

11236J *Deferasirox Juno, JU* – **DEFERASIROX**, deferasirox 125 mg dispersible tablet, 28

11241P *Deferasirox Juno, JU* – **DEFERASIROX**, deferasirox 125 mg dispersible tablet, 28

6500D *Deferasirox Juno, JU* – **DEFERASIROX**, deferasirox 250 mg dispersible tablet, 28

11238L *Deferasirox Juno, JU* – **DEFERASIROX**, deferasirox 250 mg dispersible tablet, 28

11244T *Deferasirox Juno, JU* – **DEFERASIROX**, deferasirox 250 mg dispersible tablet, 28

Deletion – Restriction

14900F **EFLORNITHINE**, eflornithine 192 mg tablet, 100 *(Ifinwil)*

Alterations

Alteration – Note

6101D **CLOZAPINE**, clozapine 25 mg tablet, 100 *(Clopine 25, Clozaril 25, Clozitor)*

6417R **CLOZAPINE**, clozapine 50 mg tablet, 100 *(Clopine 50, Clozitor)*

9632Y **CLOZAPINE**, clozapine 50 mg/mL oral liquid, 100 mL *(Clopine Suspension)*

6102E **CLOZAPINE**, clozapine 100 mg tablet, 100 *(Clopine 100, Clozaril 100, Clozitor)*

6418T **CLOZAPINE**, clozapine 200 mg tablet, 100 *(Clopine 200, Clozitor)*

9612X **INFLIXIMAB**, infliximab 100 mg injection, 1 vial *(Inflectra, Ixifi, Remicade, Remsima, Renflexis)*

11450P **INFLIXIMAB**, infliximab 100 mg injection, 1 vial *(Inflectra, Ixifi, Remicade, Remsima, Renflexis)*

Alteration – Restriction

13163T **BUROSUMAB**, burosumab 10 mg/mL injection, 1 mL vial *(Crysvita)*

13136J **BUROSUMAB**, burosumab 20 mg/mL injection, 1 mL vial *(Crysvita)*

13154H **BUROSUMAB**, burosumab 30 mg/mL injection, 1 mL vial *(Crysvita)*

9612X **INFLIXIMAB**, infliximab 100 mg injection, 1 vial *(Inflectra, Ixifi, Remicade, Remsima, Renflexis)*

11450P **INFLIXIMAB**, infliximab 100 mg injection, 1 vial *(Inflectra, Ixifi, Remicade, Remsima, Renflexis)*

11795T **TEDUGLUTIDE**, teduglutide 5 mg injection [28 vials] (&) inert substance diluent [28 x 0.5 mL syringes], 1 pack *(Revestive)*

Supply Only

Supply Only – Period Commencing

11445J **INFLIXIMAB**, infliximab 100 mg injection, 1 vial *(Inflectra, Ixifi, Remicade, Remsima, Renflexis)*

Highly Specialised Drugs Program (Public Hospital)

Additions

Addition – Item

15422Q **BUROSUMAB**, burosumab 10 mg/mL injection, 1 mL vial *(Crysvita)*

15434H **BUROSUMAB**, burosumab 20 mg/mL injection, 1 mL vial *(Crysvita)*

15480R **BUROSUMAB**, burosumab 30 mg/mL injection, 1 mL vial *(Crysvita)*

15487D **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

15451F **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

15452G **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

15428B **LENALIDOMIDE**, lenalidomide 20 mg capsule, 21 *(Lenalide, Lenalidomide Sandoz)*

15482W **NITISINONE**, nitisinone 2 mg capsule, 60 *(Orfadin)*

15426X **NITISINONE**, nitisinone 4 mg/mL oral liquid, 90 mL *(Orfadin)*

15460Q **NITISINONE**, nitisinone 5 mg capsule, 60 *(Orfadin)*

15435J **NITISINONE**, nitisinone 10 mg capsule, 60 *(Orfadin)*

15501W **NITISINONE**, nitisinone 20 mg capsule, 60 *(Orfadin)*

15469E **PEGUNIGALSIDASE ALFA**, Pegunigalsidase alfa 20 mg/10 mL injection, 10 mL vial *(ELFABRIO)*

Addition – Brand

11449N *Remicade, JC* – **INFLIXIMAB**, infliximab 100 mg injection, 1 vial

Deletions

Deletion – Item

14264R **PATISIRAN**, patisiran 10 mg/5 mL injection, 5 mL vial *(Onpattro)*

Deletion – Brand

5607D *Cipla Ambrisentan, ZU* – **AMBRISENTAN**, ambrisentan 5 mg tablet, 30

12212R *Cipla Ambrisentan, ZU* – **AMBRISENTAN**, ambrisentan 5 mg tablet, 30

5654N *Pharmacor Deferasirox, CR* – **DEFERASIROX**, deferasirox 125 mg dispersible tablet, 28

11235H *Pharmacor Deferasirox, CR* – **DEFERASIROX**, deferasirox 125 mg dispersible tablet, 28

11247Y *Pharmacor Deferasirox, CR* – **DEFERASIROX**, deferasirox 125 mg dispersible tablet, 28

5655P *Pharmacor Deferasirox, CR* – **DEFERASIROX**, deferasirox 250 mg dispersible tablet, 28

11239M *Pharmacor Deferasirox, CR* – **DEFERASIROX**, deferasirox 250 mg dispersible tablet, 28

11240N *Pharmacor Deferasirox, CR* – **DEFERASIROX**, deferasirox 250 mg dispersible tablet, 28

Deletion – Equivalence Indicator

5654N *Deferasirox Juno, JU* – **DEFERASIROX**, deferasirox 125 mg dispersible tablet, 28

11235H *Deferasirox Juno, JU* – **DEFERASIROX**, deferasirox 125 mg dispersible tablet, 28

11247Y *Deferasirox Juno, JU* – **DEFERASIROX**, deferasirox 125 mg dispersible tablet, 28

5655P *Deferasirox Juno, JU* – **DEFERASIROX**, deferasirox 250 mg dispersible tablet, 28

11239M *Deferasirox Juno, JU* – **DEFERASIROX**, deferasirox 250 mg dispersible tablet, 28

11240N *Deferasirox Juno, JU* – **DEFERASIROX**, deferasirox 250 mg dispersible tablet, 28

Deletion – Restriction

14894X **EFLORNITHINE**, eflornithine 192 mg tablet, 100 *(Ifinwil)*

Alterations

Alteration – Note

5628F **CLOZAPINE**, clozapine 25 mg tablet, 100 *(Clopine 25, Clozaril 25, Clozitor)*

5626D **CLOZAPINE**, clozapine 50 mg tablet, 100 *(Clopine 50, Clozitor)*

5630H **CLOZAPINE**, clozapine 50 mg/mL oral liquid, 100 mL *(Clopine Suspension)*

5629G **CLOZAPINE**, clozapine 100 mg tablet, 100 *(Clopine 100, Clozaril 100, Clozitor)*

5627E **CLOZAPINE**, clozapine 200 mg tablet, 100 *(Clopine 200, Clozitor)*

5755X **INFLIXIMAB**, infliximab 100 mg injection, 1 vial *(Inflectra, Ixifi, Remicade, Remsima, Renflexis)*

11449N **INFLIXIMAB**, infliximab 100 mg injection, 1 vial *(Inflectra, Ixifi, Remicade, Remsima, Renflexis)*

Alteration – Restriction

13140N **BUROSUMAB**, burosumab 10 mg/mL injection, 1 mL vial *(Crysvita)*

13145W **BUROSUMAB**, burosumab 20 mg/mL injection, 1 mL vial *(Crysvita)*

13155J **BUROSUMAB**, burosumab 30 mg/mL injection, 1 mL vial *(Crysvita)*

5755X **INFLIXIMAB**, infliximab 100 mg injection, 1 vial *(Inflectra, Ixifi, Remicade, Remsima, Renflexis)*

11449N **INFLIXIMAB**, infliximab 100 mg injection, 1 vial *(Inflectra, Ixifi, Remicade, Remsima, Renflexis)*

11793Q **TEDUGLUTIDE**, teduglutide 5 mg injection [28 vials] (&) inert substance diluent [28 x 0.5 mL syringes], 1 pack *(Revestive)*

Supply Only

Supply Only – Period Commencing

11448M **INFLIXIMAB**, infliximab 100 mg injection, 1 vial *(Inflectra, Ixifi, Remicade, Remsima, Renflexis)*

Highly Specialised Drugs Program (Community Access)

Alterations

Alteration – Note

10289M **CLOZAPINE**, clozapine 25 mg tablet, 100 *(Clopine 25, Clozaril 25, Clozitor)*

10302F **CLOZAPINE**, clozapine 50 mg tablet, 100 *(Clopine 50, Clozitor)*

10341G **CLOZAPINE**, clozapine 50 mg/mL oral liquid, 100 mL *(Clopine Suspension)*

10358E **CLOZAPINE**, clozapine 100 mg tablet, 100 *(Clopine 100, Clozaril 100, Clozitor)*

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

Advance Notices

1 September 2026

Deletion – Brand

10311Q *Lamivudine Alphapharm, AF* – **LAMIVUDINE**, lamivudine 300 mg tablet, 30

General Pharmaceutical Benefits

▪ABALOPARATIDE

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

Severe established osteoporosis

Treatment Phase: Initial treatment - Second-line therapy

Treatment criteria:

- Must be treated by a consultant physician.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with any of: (i) teriparatide, (ii) romosozumab or (iii) abaloparatide; **OR**
- Patient must have developed intolerance to (i) teriparatide, or (ii) romosozumab of a severity necessitating permanent treatment withdrawal within the first 6 months of therapy, **AND**
- Patient must be at very high risk of fracture, **AND**
- Patient must have a bone mineral density (BMD) T-score of -3.0 or less, **AND**
- Patient must have had 2 or more fractures due to minimal trauma, **AND**
- Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must not exceed a lifetime maximum of 18 months of PBS and non-PBS-subsidised therapy with this drug for this condition.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with this drug is initiated.

If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details must be documented in the patient's medical record at the time treatment with this drug is initiated.

Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months and zoledronic acid 5 mg per annum.

Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be provided at the time of application.

Authority Required

Severe established osteoporosis

Treatment Phase: Continuing treatment - Second-line therapy

Treatment criteria:

- Must be treated by a medical practitioner identifying as either: (i) a consultant physician, (ii) a general practitioner.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition as second-line therapy, **AND**
- The treatment must not exceed a lifetime maximum of 18 months of PBS and non-PBS-subsidised therapy with this drug for this condition.

Abaloparatide 2 mg/mL injection, 1.5 mL pen device

15436K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	0.00	387.19	25.00	Eladynos [TT]

▪ABALOPARATIDE

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

Severe established osteoporosis

Treatment Phase: Initial treatment - First-line therapy

Treatment criteria:

- Must be treated by a consultant physician.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with any of: (i) anti-resorptive therapy, (ii) teriparatide, (iii) romosozumab, or (iv) abaloparatide; **OR**
- Patient must have developed intolerance to romosozumab of a severity necessitating permanent treatment withdrawal within the first 6 months of therapy, **AND**
- Patient must be at very high risk of fracture, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must have had a symptomatic fracture due to minimal trauma, **AND**
- Patient must have had at least 1 hip or symptomatic vertebral fracture in the previous 24 months; **OR**
- Patient must have had at least 2 fractures including 1 symptomatic new fracture in the previous 24 months, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must not exceed a lifetime maximum of 18 months of PBS and non-PBS-subsidised therapy with this drug for this condition.

Details of fracture history including the date(s), site(s), the symptoms associated with the fracture(s) and the score of the qualifying BMD measurement must be provided at the time of application.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Anti-resorptive therapies for osteoporosis include alendronate sodium, risedronate sodium, raloxifene hydrochloride, denosumab and zoledronic acid.

Authority Required

Severe established osteoporosis

Treatment Phase: Continuing treatment - First-line therapy

Treatment criteria:

- Must be treated by a medical practitioner identifying as either: (i) a consultant physician, (ii) a general practitioner.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition as first-line therapy, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must not exceed a lifetime maximum of 18 months of PBS and non-PBS-subsidised therapy with this drug for this condition.

Abaloparatide 2 mg/mL injection, 1.5 mL pen device

15468D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	0.00	387.19	25.00	Eladynos [TT]

▪ADALIMUMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for 'severe Crohn disease' and infliximab for 'moderate to severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time or Initial 3 type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if 3 trials of a targeted therapy do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies. A paediatric patient cannot trial and not demonstrate an adequate response, or cease to respond to, the same PBS-subsidised targeted therapy more than twice.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

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

Treatment Phases:

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks for infliximab.

Initial 1 - use when the patient has never received a PBS-subsidised targeted therapy for these indications. Inadequate response to conventional therapy must be demonstrated where required.

Initial 2 - use when:

- an alternative targeted therapy is being prescribed for these indications; or
- the patient has previously been treated with this targeted therapy; or
- treatment is resuming after a break of less than 12 months

Patients applying through this treatment phase do not have to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Inadequate response to conventional therapy does not need to be redemonstrated.

Initial 3 - use when treatment is resuming after a break in PBS-subsidised treatment of at least 12 months. Patients applying through this treatment phase must requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Re-trial of conventional therapies is not required.

Continuing treatment - use when a patient has demonstrated an adequate response to the preceding supply. Patients are eligible for up to 24 weeks of treatment per continuing prescription. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Baseline measurements to determine response - a response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements provided in the first authority application for a targeted therapy. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recency of assessments:

Where possible, all related assessment documentation (including the Paediatric Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

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 Authority applications for increased quantities/repeats may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

Authority Required

Severe Crohn disease

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient treatment with this drug for this condition under any relevant initial restriction (Initial 1, 2 or 3), **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12379M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	495.79	25.00	[a] Hadlima [RF]	[a] Humira [VE]
					[a] Hyrimoz [SZ]	[a] Yuflyma [EW]

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

10399H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	495.79	25.00	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	

▪ADALIMUMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for 'severe Crohn disease' and infliximab for 'moderate to severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time or Initial 3 type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if 3 trials of a targeted therapy do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies. A paediatric patient cannot trial and not demonstrate an adequate response, or cease to respond to, the same PBS-subsidised targeted therapy more than twice.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

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

Treatment Phases:

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks for infliximab.

Initial 1 - use when the patient has never received a PBS-subsidised targeted therapy for these indications. Inadequate response to conventional therapy must be demonstrated where required.

Initial 2 - use when:

- an alternative targeted therapy is being prescribed for these indications; or
- the patient has previously been treated with this targeted therapy; or
- treatment is resuming after a break of less than 12 months

Patients applying through this treatment phase do not have to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Inadequate response to conventional therapy does not need to be redemonstrated.

Initial 3 - use when treatment is resuming after a break in PBS-subsidised treatment of at least 12 months. Patients applying through this treatment phase must requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Re-trial of conventional therapies is not required.

Continuing treatment - use when a patient has demonstrated an adequate response to the preceding supply. Patients are eligible for up to 24 weeks of treatment per continuing prescription. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Baseline measurements to determine response - a response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements provided in the first authority application for a targeted therapy. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recency of assessments:

Where possible, all related assessment documentation (including the Paediatric Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

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 Authority applications for increased quantities/repeats may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

Authority Required

Severe Crohn disease

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient treatment with this drug for this condition under any relevant initial restriction (Initial 1, 2 or 3), **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12411F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	495.79	25.00	[a] Hadlima [RF]	[a] Humira [VE]
					[a] Hyrimoz [SZ]	[a] Yuflyma [EW]

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

10400J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	495.79	25.00	[a] Abrilada [PF]	[a] Amgevita [XT]
					[a] Hadlima [RF]	[a] Hyrimoz [SZ]

▪ADALIMUMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for 'severe Crohn disease' and infliximab for 'moderate to severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time or Initial 3 type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if 3 trials of a targeted therapy do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies. A paediatric patient cannot trial and not demonstrate an adequate response, or cease to respond to, the same PBS-subsidised targeted therapy more than twice.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

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

Treatment Phases:

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks for infliximab.

Initial 1 - use when the patient has never received a PBS-subsidised targeted therapy for these indications. Inadequate response to conventional therapy must be demonstrated where required.

Initial 2 - use when:

- an alternative targeted therapy is being prescribed for these indications; or
- the patient has previously been treated with this targeted therapy; or
- treatment is resuming after a break of less than 12 months

Patients applying through this treatment phase do not have to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Inadequate response to conventional therapy does not need to be redemonstrated.

Initial 3 - use when treatment is resuming after a break in PBS-subsidised treatment of at least 12 months. Patients applying through this treatment phase must requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Re-trial of conventional therapies is not required.

Continuing treatment - use when a patient has demonstrated an adequate response to the preceding supply. Patients are eligible for up to 24 weeks of treatment per continuing prescription. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Baseline measurements to determine response - a response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements provided in the first authority application for a targeted therapy. However, prescribers may provide new baseline measurements any time that an initial treatment authority

application is made within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recency of assessments:

Where possible, all related assessment documentation (including the Paediatric Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

Note Pharmaceutical benefits that have the form adalimumab 20 mg/0.2 mL syringes and pharmaceutical benefits that have the form adalimumab 20 mg/0.4 mL syringes are equivalent for the purposes of substitution

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

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 Authority applications for increased quantities/repeats may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

Authority Required

Severe Crohn disease

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient treatment with this drug for this condition under any relevant initial restriction (Initial 1, 2 or 3), **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes

12423W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	0	0.00	630.77	25.00	[a] Humira [VE]

adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe

12354F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	0	0.00	*606.96	25.00	[a] Amgevita [XT]

▪ADALIMUMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for 'severe Crohn disease' and infliximab for 'moderate to severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time or Initial 3 type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if 3 trials of a targeted therapy do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies. A paediatric patient cannot trial and not demonstrate an adequate response, or cease to respond to, the same PBS-subsidised targeted therapy more than twice.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

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

Treatment Phases:

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks for infliximab.

Initial 1 - use when the patient has never received a PBS-subsidised targeted therapy for these indications. Inadequate response to conventional therapy must be demonstrated where required.

Initial 2 - use when:

- an alternative targeted therapy is being prescribed for these indications; or
- the patient has previously been treated with this targeted therapy; or

- treatment is resuming after a break of less than 12 months

Patients applying through this treatment phase do not have to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Inadequate response to conventional therapy does not need to be redemonstrated.

Initial 3 - use when treatment is resuming after a break in PBS-subsidised treatment of at least 12 months. Patients applying through this treatment phase must requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Re-trial of conventional therapies is not required.

Continuing treatment - use when a patient has demonstrated an adequate response to the preceding supply. Patients are eligible for up to 24 weeks of treatment per continuing prescription. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Baseline measurements to determine response - a response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements provided in the first authority application for a targeted therapy. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recency of assessments:

Where possible, all related assessment documentation (including the Paediatric Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

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).

Note Authority applications for increased quantities may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

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

Authority Required (STREAMLINED)

18991

Severe Crohn disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must have both: (i) a total PCDAI score of 40 points or less, and (ii) a reduction in PCDAI score by at least 15 points from baseline value; **OR**
- Patient must have an adequate response to this drug defined as an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

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

If a patient does not demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition under this treatment phase. Patients may re-trial treatment with this drug under the 'Initial 2' treatment phase if eligible. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13224B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	495.79	25.00	[a] Hadlima [RF]	[a] Humira [VE]
					[a] Hyrimoz [SZ]	[a] Yuflyma [EW]

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

12420Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	495.79	25.00	[a] Abrilada [PF]	[a] Amgevita [XT]
					[a] Hadlima [RF]	[a] Hyrimoz [SZ]

▪ADALIMUMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for 'severe Crohn disease' and infliximab for 'moderate to severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time or Initial 3 type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if 3 trials of a targeted therapy do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies. A paediatric patient cannot trial and not demonstrate an adequate response, or cease to respond to, the same PBS-subsidised targeted therapy more than twice.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

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

Treatment Phases:

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks for infliximab.

Initial 1 - use when the patient has never received a PBS-subsidised targeted therapy for these indications. Inadequate response to conventional therapy must be demonstrated where required.

Initial 2 - use when:

- an alternative targeted therapy is being prescribed for these indications; or
- the patient has previously been treated with this targeted therapy; or
- treatment is resuming after a break of less than 12 months

Patients applying through this treatment phase do not have to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Inadequate response to conventional therapy does not need to be redemonstrated.

Initial 3 - use when treatment is resuming after a break in PBS-subsidised treatment of at least 12 months. Patients applying through this treatment phase must requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Re-trial of conventional therapies is not required.

Continuing treatment - use when a patient has demonstrated an adequate response to the preceding supply. Patients are eligible for up to 24 weeks of treatment per continuing prescription. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Baseline measurements to determine response - a response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements provided in the first authority application for a targeted therapy. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recency of assessments:

Where possible, all related assessment documentation (including the Paediatric Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

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).

Note Authority applications for increased quantities may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

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

Authority Required (STREAMLINED)

18991

Severe Crohn disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must have both: (i) a total PCDAI score of 40 points or less, and (ii) a reduction in PCDAI score by at least 15 points from baseline value; **OR**
- Patient must have an adequate response to this drug defined as an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

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

If a patient does not demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition under this treatment phase. Patients may re-trial treatment with this drug under the 'Initial 2' treatment phase if eligible. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13218Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	495.79	25.00	[a] Hadlima [RF]	[a] Humira [VE]
					[a] Hyrimoz [SZ]	[a] Yuflyma [EW]

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

12434K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	495.79	25.00	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	

▪ ADALIMUMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for 'severe Crohn disease' and infliximab for 'moderate to severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time or Initial 3 type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if 3 trials of a targeted therapy do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies. A paediatric patient cannot trial and not demonstrate an adequate response, or cease to respond to, the same PBS-subsidised targeted therapy more than twice.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

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

Treatment Phases:

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks for infliximab.

Initial 1 - use when the patient has never received a PBS-subsidised targeted therapy for these indications. Inadequate response to conventional therapy must be demonstrated where required.

Initial 2 - use when:

- an alternative targeted therapy is being prescribed for these indications; or
- the patient has previously been treated with this targeted therapy; or
- treatment is resuming after a break of less than 12 months

Patients applying through this treatment phase do not have to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Inadequate response to conventional therapy does not need to be redemonstrated.

Initial 3 - use when treatment is resuming after a break in PBS-subsidised treatment of at least 12 months. Patients applying through this treatment phase must requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Re-trial of conventional therapies is not required.

Continuing treatment - use when a patient has demonstrated an adequate response to the preceding supply. Patients are eligible for up to 24 weeks of treatment per continuing prescription. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Baseline measurements to determine response - a response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements provided in the first authority application for a targeted therapy. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recency of assessments:

Where possible, all related assessment documentation (including the Paediatric Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

Note Pharmaceutical benefits that have the form adalimumab 20 mg/0.2 mL syringes and pharmaceutical benefits that have the form adalimumab 20 mg/0.4 mL syringes are equivalent for the purposes of substitution

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

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).

Note Authority applications for increased quantities may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

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

Authority Required (STREAMLINED)

18991

Severe Crohn disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must have both: (i) a total PCDAI score of 40 points or less, and (ii) a reduction in PCDAI score by at least 15 points from baseline value; **OR**
- Patient must have an adequate response to this drug defined as an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

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

If a patient does not demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition under this treatment phase. Patients may re-trial treatment with this drug under the 'Initial 2' treatment phase if eligible. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes

14995F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	0.00	630.77	25.00	[a] Humira [VE]

adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe

12436M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	0.00	*606.96	25.00	[a] Amgevita [XT]

▪ ADALIMUMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for 'severe Crohn disease' and infliximab for 'moderate to severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time or Initial 3 type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if 3 trials of a targeted therapy do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies. A paediatric patient cannot trial and not demonstrate an adequate response, or cease to respond to, the same PBS-subsidised targeted therapy more than twice.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

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

Treatment Phases:

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks for infliximab.

Initial 1 - use when the patient has never received a PBS-subsidised targeted therapy for these indications. Inadequate response to conventional therapy must be demonstrated where required.

Initial 2 - use when:

- an alternative targeted therapy is being prescribed for these indications; or
- the patient has previously been treated with this targeted therapy; or
- treatment is resuming after a break of less than 12 months

Patients applying through this treatment phase do not have to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Inadequate response to conventional therapy does not need to be redemonstrated.

Initial 3 - use when treatment is resuming after a break in PBS-subsidised treatment of at least 12 months. Patients applying through this treatment phase must requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Re-trial of conventional therapies is not required.

Continuing treatment - use when a patient has demonstrated an adequate response to the preceding supply. Patients are eligible for up to 24 weeks of treatment per continuing prescription. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Baseline measurements to determine response - a response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements provided in the first authority application for a targeted therapy. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recency of assessments:

Where possible, all related assessment documentation (including the Paediatric Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note At the time of authority application, medical practitioners must request the appropriate number of doses to provide sufficient drug for 16 weeks of treatment.

An appropriate amount of drug may require prescribing a combination of strengths. A separate authority prescription must be completed for each strength requested.

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 Authority applications for increased quantities may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

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

Authority Required

Severe Crohn disease

Treatment Phase: Initial 1 (new patient)

Clinical criteria:

- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must not have achieved an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy with a thiopurine at a clinically optimised dose, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; **OR**
- Patient must have a documented contraindication to each of prednisolone (or equivalent), a thiopurine, and methotrexate; **OR**
- Patient must have features of high-risk or complicated Crohn disease defined as those with any of the following: (i) perianal disease, (ii) stricturing or penetrating behaviour, (iii) severe delayed growth (growth velocity at least 2 standard deviations below the mean for age and sex, or a drop of at least 1 major centile band), **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40; **OR**
- Patient must have extensive intestinal inflammation of the small intestine as evidenced by radiological imaging, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

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

(b) current PCDAI score and the date of assessment; or

(c) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

For patients assessed as having extensive intestinal inflammation of the small intestines, such evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant contraindications or precautions in the TGA-approved Product Information, please provide details at the time of application. Patients must attempt to trial alternate conventional therapies that are not contraindicated.

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

Where a response assessment is not conducted, the patient will be deemed to have not responded to treatment with this drug. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Authority Required

Severe Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must not have previously received this drug for this condition in this treatment cycle; **OR**
- Patient must have previously received this drug for this condition and demonstrated/maintained an adequate clinical response; **OR**
- Patient must have: (i) received this drug in this treatment cycle, (ii) not demonstrated/maintained an adequate response to this drug once in this treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, the PCDAI score and the date of assessment; or

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' clinical and treatment criteria when targeted therapy treatment commenced. The following information must also be provided at the time of application:

(a) the baseline PCDAI score and the date of assessment; or

(b) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

Where a response assessment is not conducted, the patient will be deemed to have not responded to treatment with this drug. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Authority Required

Severe Crohn disease

Treatment Phase: Initial 3 (recommencement of treatment after a break in targeted therapy of more than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised targeted therapy for this condition, **AND**
- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must have disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 while off treatment with targeted therapy; **OR**
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease while off treatment with targeted therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) current PCDAI score and the date of assessment; or

(b) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

For patients assessed as having extensive intestinal inflammation of the small intestines, such evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where a response assessment is not conducted, the patient will be deemed to have not responded to treatment with this drug. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe

12409D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3	0	0.00	*2042.73	25.00	[a] Humira [VE]	[a] Yuflyma [EW]

adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device

12426B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3	0	0.00	*2042.73	25.00	[a] Humira [VE]	[a] Hyrimoz [SZ]
					[a] Yuflyma [EW]	

▪ADALIMUMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for 'severe Crohn disease' and infliximab for 'moderate to severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time or Initial 3 type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if 3 trials of a targeted therapy do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies. A paediatric patient cannot trial and not demonstrate an adequate response, or cease to respond to, the same PBS-subsidised targeted therapy more than twice.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

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

Treatment Phases:

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks for infliximab.

Initial 1 - use when the patient has never received a PBS-subsidised targeted therapy for these indications. Inadequate response to conventional therapy must be demonstrated where required.

Initial 2 - use when:

- an alternative targeted therapy is being prescribed for these indications; or
- the patient has previously been treated with this targeted therapy; or
- treatment is resuming after a break of less than 12 months

Patients applying through this treatment phase do not have to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Inadequate response to conventional therapy does not need to be redemonstrated.

Initial 3 - use when treatment is resuming after a break in PBS-subsidised treatment of at least 12 months. Patients applying through this treatment phase must requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Re-trial of conventional therapies is not required.

Continuing treatment - use when a patient has demonstrated an adequate response to the preceding supply. Patients are eligible for up to 24 weeks of treatment per continuing prescription. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Baseline measurements to determine response - a response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements provided in the first authority application for a targeted therapy. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recency of assessments:

Where possible, all related assessment documentation (including the Paediatric Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note At the time of authority application, medical practitioners must request the appropriate number of doses to provide sufficient drug for 16 weeks of treatment.

An appropriate amount of drug may require prescribing a combination of strengths. A separate authority prescription must be completed for each strength requested.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

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 Authority applications for increased quantities may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

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

Authority Required

Severe Crohn disease

Treatment Phase: Initial 1 (new patient)

Clinical criteria:

- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must not have achieved an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy with a thiopurine at a clinically optimised dose, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; **OR**
- Patient must have a documented contraindication to each of prednisolone (or equivalent), a thiopurine, and methotrexate; **OR**
- Patient must have features of high-risk or complicated Crohn disease defined as those with any of the following: (i) perianal disease, (ii) stricturing or penetrating behaviour, (iii) severe delayed growth (growth velocity at least 2 standard deviations below the mean for age and sex, or a drop of at least 1 major centile band), **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40; **OR**
- Patient must have extensive intestinal inflammation of the small intestine as evidenced by radiological imaging, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

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

(b) current PCDAI score and the date of assessment; or

(c) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

For patients assessed as having extensive intestinal inflammation of the small intestines, such evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant contraindications or precautions in the TGA-approved Product Information, please provide details at the time of application. Patients must attempt to trial alternate conventional therapies that are not contraindicated.

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

Where a response assessment is not conducted, the patient will be deemed to have not responded to treatment with this drug. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Authority Required

Severe Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must not have previously received this drug for this condition in this treatment cycle; **OR**

- Patient must have previously received this drug for this condition and demonstrated/maintained an adequate clinical response; **OR**
- Patient must have: (i) received this drug in this treatment cycle, (ii) not demonstrated/maintained an adequate response to this drug once in this treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, the PCDAI score and the date of assessment; or

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' clinical and treatment criteria when targeted therapy treatment commenced. The following information must also be provided at the time of application:

(a) the baseline PCDAI score and the date of assessment; or

(b) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

Where a response assessment is not conducted, the patient will be deemed to have not responded to treatment with this drug. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Authority Required

Severe Crohn disease

Treatment Phase: Initial 3 (recommencement of treatment after a break in targeted therapy of more than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised targeted therapy for this condition, **AND**
- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must have disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 while off treatment with targeted therapy; **OR**
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease while off treatment with targeted therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) current PCDAI score and the date of assessment; or

(b) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

For patients assessed as having extensive intestinal inflammation of the small intestines, such evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where a response assessment is not conducted, the patient will be deemed to have not responded to treatment with this drug. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12373F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	0.00	495.79	25.00	[a] Hadlima [RF]	[a] Humira [VE]
					[a] Hyrimoz [SZ]	[a] Yuflyma [EW]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12432H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3	0	0.00	*1468.65	25.00	[a] Hadlima [RF]	[a] Humira [VE]
					[a] Hyrimoz [SZ]	[a] Yuflyma [EW]

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

10413C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	0.00	495.79	25.00	[a] Abrilada [PF]	[a] Amgevita [XT]
					[a] Hadlima [RF]	[a] Hyrimoz [SZ]

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

12388B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3	0	0.00	*1468.65	25.00	[a] Abrilada [PF]	[a] Amgevita [XT]
					[a] Hadlima [RF]	[a] Hyrimoz [SZ]

▪ ADALIMUMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for 'severe Crohn disease' and infliximab for 'moderate to severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time or Initial 3 type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if 3 trials of a targeted therapy do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies. A paediatric patient cannot trial and not demonstrate an adequate response, or cease to respond to, the same PBS-subsidised targeted therapy more than twice.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

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

Treatment Phases:

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks for infliximab.

Initial 1 - use when the patient has never received a PBS-subsidised targeted therapy for these indications. Inadequate response to conventional therapy must be demonstrated where required.

Initial 2 - use when:

- an alternative targeted therapy is being prescribed for these indications; or
- the patient has previously been treated with this targeted therapy; or
- treatment is resuming after a break of less than 12 months

Patients applying through this treatment phase do not have to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Inadequate response to conventional therapy does not need to be redemonstrated.

Initial 3 - use when treatment is resuming after a break in PBS-subsidised treatment of at least 12 months. Patients applying through this treatment phase must requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Re-trial of conventional therapies is not required.

Continuing treatment - use when a patient has demonstrated an adequate response to the preceding supply. Patients are eligible for up to 24 weeks of treatment per continuing prescription. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Baseline measurements to determine response - a response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements provided in the first authority application for a targeted therapy. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recency of assessments:

Where possible, all related assessment documentation (including the Paediatric Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note At the time of authority application, medical practitioners must request the appropriate number of doses to provide sufficient drug for 16 weeks of treatment.

An appropriate amount of drug may require prescribing a combination of strengths. A separate authority prescription must be completed for each strength requested.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

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 Authority applications for increased quantities may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

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

Authority Required

Severe Crohn disease

Treatment Phase: Initial 1 (new patient)

Clinical criteria:

- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must not have achieved an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy with a thiopurine at a clinically optimised dose, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; **OR**
- Patient must have a documented contraindication to each of prednisolone (or equivalent), a thiopurine, and methotrexate; **OR**
- Patient must have features of high-risk or complicated Crohn disease defined as those with any of the following: (i) perianal disease, (ii) stricturing or penetrating behaviour, (iii) severe delayed growth (growth velocity at least 2 standard deviations below the mean for age and sex, or a drop of at least 1 major centile band), **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40; **OR**
- Patient must have extensive intestinal inflammation of the small intestine as evidenced by radiological imaging, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

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

(b) current PCDAI score and the date of assessment; or

(c) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

For patients assessed as having extensive intestinal inflammation of the small intestines, such evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant contraindications or precautions in the TGA-approved Product Information, please provide details at the time of application. Patients must attempt to trial alternate conventional therapies that are not contraindicated.

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

Where a response assessment is not conducted, the patient will be deemed to have not responded to treatment with this drug. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Authority Required

Severe Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must not have previously received this drug for this condition in this treatment cycle; **OR**
- Patient must have previously received this drug for this condition and demonstrated/maintained an adequate clinical response; **OR**
- Patient must have: (i) received this drug in this treatment cycle, (ii) not demonstrated/maintained an adequate response to this drug once in this treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, the PCDAI score and the date of assessment; or

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' clinical and treatment criteria when targeted therapy treatment commenced. The following information must also be provided at the time of application:

(a) the baseline PCDAI score and the date of assessment; or

(b) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

Where a response assessment is not conducted, the patient will be deemed to have not responded to treatment with this drug. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Authority Required

Severe Crohn disease

Treatment Phase: Initial 3 (recommencement of treatment after a break in targeted therapy of more than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised targeted therapy for this condition, **AND**
- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must have disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 while off treatment with targeted therapy; **OR**
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease while off treatment with targeted therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) current PCDAI score and the date of assessment; or

(b) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

For patients assessed as having extensive intestinal inflammation of the small intestines, such evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where a response assessment is not conducted, the patient will be deemed to have not responded to treatment with this drug. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12338J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	0.00	495.79	25.00	[a] Hadlima [RF]	[a] Humira [VE]
						[a] Hyrimoz [SZ]	[a] Yuflyma [EW]

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12455M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	0	0.00	*1468.65	25.00	[a] Hadlima [RF]	[a] Humira [VE]
						[a] Hyrimoz [SZ]	[a] Yuflyma [EW]

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

10419J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	0.00	495.79	25.00	[a] Amgevita [XT]	[a] Hadlima [RF]
						[a] Hyrimoz [SZ]	

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

12416L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	0	0.00	*1468.65	25.00	[a] Amgevita [XT]	[a] Hadlima [RF]
						[a] Hyrimoz [SZ]	

▪ADALIMUMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for 'severe Crohn disease' and infliximab for 'moderate to severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time or Initial 3 type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if 3 trials of a targeted therapy do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies. A paediatric patient cannot trial and not demonstrate an adequate response, or cease to respond to, the same PBS-subsidised targeted therapy more than twice.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

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

Treatment Phases:

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks for infliximab.

Initial 1 - use when the patient has never received a PBS-subsidised targeted therapy for these indications. Inadequate response to conventional therapy must be demonstrated where required.

Initial 2 - use when:

- an alternative targeted therapy is being prescribed for these indications; or
- the patient has previously been treated with this targeted therapy; or

- treatment is resuming after a break of less than 12 months

Patients applying through this treatment phase do not have to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Inadequate response to conventional therapy does not need to be redemonstrated.

Initial 3 - use when treatment is resuming after a break in PBS-subsidised treatment of at least 12 months. Patients applying through this treatment phase must requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Re-trial of conventional therapies is not required.

Continuing treatment - use when a patient has demonstrated an adequate response to the preceding supply. Patients are eligible for up to 24 weeks of treatment per continuing prescription. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Baseline measurements to determine response - a response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements provided in the first authority application for a targeted therapy. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recency of assessments:

Where possible, all related assessment documentation (including the Paediatric Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note At the time of authority application, medical practitioners must request the appropriate number of doses to provide sufficient drug for 16 weeks of treatment.

An appropriate amount of drug may require prescribing a combination of strengths. A separate authority prescription must be completed for each strength requested.

Note Pharmaceutical benefits that have the form adalimumab 20 mg/0.2 mL syringes and pharmaceutical benefits that have the form adalimumab 20 mg/0.4 mL syringes are equivalent for the purposes of substitution

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

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 Authority applications for increased quantities may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

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

Authority Required

Severe Crohn disease

Treatment Phase: Initial 1 (new patient)

Clinical criteria:

- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must not have achieved an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy with a thiopurine at a clinically optimised dose, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; **OR**
- Patient must have a documented contraindication to each of prednisolone (or equivalent), a thiopurine, and methotrexate; **OR**
- Patient must have features of high-risk or complicated Crohn disease defined as those with any of the following: (i) perianal disease, (ii) stricturing or penetrating behaviour, (iii) severe delayed growth (growth velocity at least 2 standard deviations below the mean for age and sex, or a drop of at least 1 major centile band), **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40; **OR**
- Patient must have extensive intestinal inflammation of the small intestine as evidenced by radiological imaging, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

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

(b) current PCDAI score and the date of assessment; or

(c) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

For patients assessed as having extensive intestinal inflammation of the small intestines, such evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant contraindications or precautions in the TGA-approved Product Information, please provide details at the time of application. Patients must attempt to trial alternate conventional therapies that are not contraindicated.

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

Where a response assessment is not conducted, the patient will be deemed to have not responded to treatment with this drug. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Authority Required

Severe Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must not have previously received this drug for this condition in this treatment cycle; **OR**
- Patient must have previously received this drug for this condition and demonstrated/maintained an adequate clinical response; **OR**
- Patient must have: (i) received this drug in this treatment cycle, (ii) not demonstrated/maintained an adequate response to this drug once in this treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, the PCDAI score and the date of assessment; or

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' clinical and treatment criteria when targeted therapy treatment commenced. The following information must also be provided at the time of application:

(a) the baseline PCDAI score and the date of assessment; or

(b) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

Where a response assessment is not conducted, the patient will be deemed to have not responded to treatment with this drug. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Authority Required

Severe Crohn disease

Treatment Phase: Initial 3 (recommencement of treatment after a break in targeted therapy of more than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised targeted therapy for this condition, **AND**
- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must have disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 while off treatment with targeted therapy; **OR**
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease while off treatment with targeted therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) current PCDAI score and the date of assessment; or

(b) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

For patients assessed as having extensive intestinal inflammation of the small intestines, such evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where a response assessment is not conducted, the patient will be deemed to have not responded to treatment with this drug. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes

12407B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	0.00	630.77	25.00	[a] Humira [VE]

adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe

12332C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	3	0.00	*606.96	25.00	[a] Amgevita [XT]

▪CLOPIDOGREL

Note Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution.

clopidogrel 75 mg tablet, 28

8358X

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	18.40	19.94	[a] Blooms Clopidogrel [BG]	[a] Clopidogrel Lupin [GQ]
					[a] Clopidogrel Sandoz Pharma [HX]	[a] Clopidogrel Winthrop [WA]
					[a] Iscover [AV]	[a] Piax [AF]
					[a] Plavicor 75 [CR]	

clopidogrel 75 mg tablet, 28

9354H

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	18.40	19.94	[a] CLOPIDOGREL-WGR [WG]	[a] Clovix 75 [RW]
					[a] Plidogrel [RF]	

▪CLOPIDOGREL

Note Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution.

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

clopidogrel 75 mg tablet, 28

13365K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*22.44	23.98	[a] CLOPIDOGREL-WGR [WG]	[a] Clovix 75 [RW]
						[a] Plidogrel [RF]	

clopidogrel 75 mg tablet, 28

13399F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*22.44	23.98	[a] Blooms Clopidogrel [BG]	[a] Clopidogrel Lupin [GQ]
						[a] Clopidogrel Sandoz Pharma [HX]	[a] Clopidogrel Winthrop [WA]
						[a] Iscover [AV]	[a] Piax [AF]
						[a] Plavicor 75 [CR]	

▪EPCORITAMAB

Caution Careful monitoring of patients is required due to risk of developing life-threatening Cytokine Release Syndrome (CRS).

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

Relapsed or refractory diffuse large B-cell lymphoma (DLBCL)

Treatment Phase: Induction treatment

Clinical criteria:

- The condition must have relapsed, or be refractory to, at least two prior systemic therapies, **AND**
- Patient must have a WHO performance status of no higher than 2, **AND**
- Patient must have previously received treatment with chimeric antigen receptor-T (CAR-T) cell therapy for this condition; **OR**
- Patient must be currently unable to receive treatment with CAR-T cell therapy for this condition, **AND**
- Patient must not be eligible for stem cell transplantation, **AND**
- Patient must not have received prior treatment with a PBS-subsidised CD20xCD3 bispecific monoclonal antibody (unless this is for a re-priming cycle with epcoritamab due to missed or delayed dose), **AND**
- The treatment must be discontinued in patients who experience disease progression whilst on treatment.

Prior systemic therapy may include autologous stem cell transplant.

Definition of patients unable to receive treatment with CAR-T cell therapy for this condition include geographical, psychosocial, clinical ineligibility or urgency.

Note A dose of 0.16 mg to be administered on Day 1 with initial 4 mg vial. A dose of 0.8 mg to be administered on Day 8 with the repeat 4 mg vial. Refer to the epcoritamab Therapeutic Goods Administration (TGA) approved Product Information.

Epcoritamab 4 mg/0.8 mL injection, 0.8 mL vial

14792M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	0.00	851.79	25.00	Epkinly [VE]

▪INFLIXIMAB

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

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

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

Note Where there is already an approved authority prescription for the IV formulation, an authority application for this subcutaneously administered form can be made under one of:

(1) The Balance of supply listing - apply under this listing if the treatment phase is yet to be completed; the following prescription is to be under a Continuing treatment listing.

(2) A Continuing treatment listing - apply under one of these types of listings where a patient is demonstrating a response to 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 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

Severe Crohn disease

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have received treatment with the PBS-subsidised IV formulation of this drug for this condition; **OR**
- Patient must have received an approved PBS authority prescription for treatment with the IV formulation of this drug for this condition; **OR**
- Patient must not have received treatment with the IV formulation of this drug, but has met the restrictions criteria as specified in the Initial 1, 2, or 3 for the IV formulation for this condition.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

The following information must be provided for patients who have not received the IV formulation as loading dose(s), but has met the restrictions criteria as specified in the Initial 1, 2, or 3 for the IV formulation:

(i) reason for loading doses being omitted; and

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

(iii) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) nominated as the response criteria; and

(iv) if applicable, details of intestinal inflammation marker/s; and

(v) if applicable, the PCDAI or CDAI score and the date of assessment; and

(vi) the date of the most recent clinical assessment.

infliximab 120 mg/mL injection, 1 mL pen device

12551N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	0.00	*562.18	25.00	Remsima SC [EW]

infliximab 120 mg/mL injection, 1 mL syringe

12585J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	0.00	*738.30	25.00	Remsima SC [EW]

▪MIGALASTAT

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

Fabry disease

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have at least one of: (i) documented deficiency of alpha-galactosidase enzyme activity in blood, (ii) presence of genetic mutations known to result in deficiency of alpha-galactosidase enzyme activity, **AND**
- Patient must have a documented migalastat amenable galactosidase alpha (GLA) gene variant, **AND**
- Patient must have an estimated glomerular filtration rate (eGFR) of at least 30 mL/min/1.73 m^2, **AND**
- Patient must be male with Fabry-related renal disease confirmed by at least one of the following: (i) abnormal albuminuria of more than 20 mcg/min, as determined by 2 separate samples at least 24 hours apart, (ii) abnormal proteinuria of more than 150 mg/24 hours, (iii) albumin:creatinine ratio greater than upper limit of normal in 2 separate samples at least 24 hours apart, (iv) renal disease due to long-term accumulation of glycosphingolipids in the kidneys; **OR**
- Patient must be female with Fabry-related renal disease confirmed by at least one of the following: (i) proteinuria of more than 300 mg/24 hours with clinical evidence of progression, (ii) renal disease due to long-term accumulation of glycosphingolipids in the kidneys; **OR**
- Patient must have Fabry-related cardiac disease confirmed by at least one of the following: (i) left ventricular hypertrophy, as evidenced by cardiac magnetic resonance imaging (MRI) or echocardiogram data, in the absence of hypertension, (ii) significant life-threatening arrhythmia or conduction defect, (iii) late gadolinium enhancement or a low T1 on cardiac MRI; **OR**
- Patient must have Fabry-related either: (i) ischaemic disease, (ii) cerebrovascular disease as shown on objective testing with no other cause or risk factors identified; **OR**
- Patient must have Fabry-related uncontrolled chronic pain despite the use of recommended doses of appropriate analgesia and antiseizure medications for peripheral neuropathy; **OR**
- Patient must have significant Fabry-related gastrointestinal symptoms despite the use of the recommended doses of appropriate pharmacological therapies, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of Fabry disease.

Population criteria:

- Patient must be at least 12 years of age.

If hypertension is present in patients relying their eligibility on Fabry-related cardiac disease, the prescriber must treat it optimally for at least 6 months prior to submitting the first PBS authority application.

Confirmation of eligibility for treatment with diagnostic reports including the confirmed mutations must be documented in the patient's medical records.

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

(1) details of the proposed prescription; and

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

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

Fabry disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, the details of which must be kept with the patient's record, **AND**
- Patient must not have developed another life threatening/severe disease where long term prognosis is unlikely to be influenced by migalastat, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of Fabry disease.

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

Fabry disease

Treatment Phase: Grandfather arrangement (transition from LSDP-funded Fabry disease therapy)

Clinical criteria:

- Patient must have previously received treatment with this drug for this condition funded under the Australian Government's Life Saving Drugs Program (LSDP) prior to 1 September 2024; **OR**
- Patient must have previously received treatment with Enzyme Replacement Therapy for this condition funded under the Australian Government's Life Saving Drugs Program (LSDP) prior to 1 September 2024, **AND**
- Patient must have a documented migalastat amenable galactosidase alpha (GLA) gene variant prior to commencing treatment with this drug, **AND**
- Patient must have/have had an estimated glomerular filtration rate (eGFR) of at least 30 mL/min/1.73 m^2 prior to commencing treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of Fabry disease.

Population criteria:

- Patient must be at least 12 years of age.

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

Confirmation of eligibility for treatment with diagnostic reports including the confirmed mutations must be documented in the patient's medical records.

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

(1) details of the proposed prescription; and

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

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

Fabry disease

Treatment Phase: Switching from PBS-subsidised pegunigalsidase alfa

Clinical criteria:

- Patient must have received prior treatment with PBS-subsidised pegunigalsidase alfa for this condition, **AND**
- Patient must not have developed another life threatening/severe disease where long term prognosis is unlikely to be influenced by this drug, **AND**
- Patient must have a documented migalastat amenable galactosidase alpha (GLA) gene variant, **AND**
- Patient must have an estimated glomerular filtration rate (eGFR) of at least 30 mL/min/1.73 m^2, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have failed to demonstrate clinical improvement or stabilisation of this condition with previous PBS-subsidised treatment with this drug.

Treatment criteria:

- Must be treated by a physician with expertise in the management of Fabry disease.

Population criteria:

- Patient must be at least 12 years of age.

Confirmation of eligibility for treatment with diagnostic reports including the confirmed mutations 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).

migalastat 123 mg capsule, 14

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14573B	1	6	0.00	28246.21	25.00	Galafold [FT]

▪OXYCODONE

Caution The risk of drug dependence is high.

Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

Note Pharmaceutical benefits that have the forms Oxycodone hydrochloride 5 mg capsule, 20 and oxycodone hydrochloride 5 mg capsule, 10 are equivalent for the purposes of substitution.

Restricted benefit

Severe pain

Clinical criteria:

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; **OR**
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

oxycodone hydrochloride 5 mg capsule, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12311Y DP	1	0	0.00	25.83	25.00	OxyNorm [MF]

oxycodone hydrochloride 5 mg capsule, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
15423R DP	0.5	0	0.00	*28.74	25.00	[a] Oxycodone BNM [BZ]	[a] OxyNorm [MF]

▪OXYCODONE

Caution The risk of drug dependence is high.

Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

Note Pharmaceutical benefits that have the forms Oxycodone hydrochloride 5 mg tablet, 20 and oxycodone hydrochloride 5 mg tablet, 10 are equivalent for the purposes of substitution.

Restricted benefit

Severe pain

Clinical criteria:

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; **OR**
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

oxycodone hydrochloride 5 mg tablet, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13234M DP	1	0	0.00	21.58	23.12	[a] Oxycodone Viatris [MQ]	
			[B]1.00	22.58	23.12	[a] ENDONE [AF]	

oxycodone hydrochloride 5 mg tablet, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
15450E DP	0.5	0	0.00	*23.33	24.87	[a] Mayne Pharma Oxycodone IR [SZ]	[a] Oxycodone Viatris [MQ]
						[a] Oxyndone [TX]	
			1.24	24.57	24.87	[a] ENDONE [AF]	

▪OXYCODONE

Caution The risk of drug dependence is high.

Note Pharmaceutical benefits that have the forms Oxycodone hydrochloride 5 mg capsule, 20 and oxycodone hydrochloride 5 mg capsule, 10 are equivalent for the purposes of substitution.

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

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

Restricted benefit

Severe pain

Clinical criteria:

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; **OR**
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

Treatment criteria:

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife who is sharing the post-operative care of the patient with a medical practitioner.

oxycodone hydrochloride 5 mg capsule, 10

12314D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP MW	1	0	0.00	25.83	25.00	OxyNorm [MF]

oxycodone hydrochloride 5 mg capsule, 20

15495M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	0.5	0	0.00	*28.74	25.00	[a] Oxycodone BNM [BZ]	[a] OxyNorm [MF]

▪OXYCODONE

Caution The risk of drug dependence is high.

Note Pharmaceutical benefits that have the forms Oxycodone hydrochloride 5 mg tablet, 20 and oxycodone hydrochloride 5 mg tablet, 10 are equivalent for the purposes of substitution.

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

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

Restricted benefit

Severe pain

Clinical criteria:

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; **OR**
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

Treatment criteria:

- Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) a nurse practitioner, (iii) an endorsed midwife who is sharing the post-operative care of the patient with a medical practitioner.

oxycodone hydrochloride 5 mg tablet, 10

13233L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	1	0	0.00	21.58	23.12	[a] Oxycodone Viatris [MQ]	
			[B]1.00	22.58	23.12	[a] ENDONE [AF]	

oxycodone hydrochloride 5 mg tablet, 20

15424T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	0.5	0	0.00	*23.33	24.87	[a] Mayne Pharma Oxycodone IR [SZ]	[a] Oxycodone Viatris [MQ]
						[a] Oxyndone [TX]	
			1.24	24.57	24.87	[a] ENDONE [AF]	

▪QUININE

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.

Authority Required

Malaria

Caution Severe thrombocytopenia has been reported with this drug.

quinine sulfate dihydrate 300 mg tablet, 50

1975Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	2	0.00	24.06	25.00	Quinate [RW]

▪ROMOSOZUMAB

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

Severe established osteoporosis

Treatment Phase: Initial treatment - Second-line therapy

Clinical criteria:

- Patient must be at very high risk of fracture, **AND**
- Patient must have a bone mineral density (BMD) T-score of -3.0 or less, **AND**
- Patient must have had 2 or more fractures due to minimal trauma, **AND**

- Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must not exceed a lifetime maximum of 12 months of PBS and non-PBS-subsidised therapy, **AND**
- Patient must not have received PBS-subsidised treatment with any of: (i) teriparatide, (ii) abaloparatide, or (iii) romosozumab; **OR**
- Patient must have developed intolerance to: (i) teriparatide, or (ii) abaloparatide of a severity necessitating permanent treatment withdrawal within the first 6 months of therapy.

Treatment criteria:

- Must be treated by a consultant physician.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with this drug is initiated.

If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details must be documented in the patient's medical record at the time treatment with this drug is initiated.

Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months and zoledronic acid 5 mg per annum.

Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be provided at the time of application.

Authority Required

Severe established osteoporosis

Treatment Phase: Continuing treatment - Second-line therapy

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition as second-line therapy, **AND**
- The treatment must not exceed a lifetime maximum of 12 months of PBS and non-PBS-subsidised therapy.

Treatment criteria:

- Must be treated by a medical practitioner identifying as either: (i) a consultant physician, (ii) a general practitioner.

romosozumab 105 mg/1.17 mL injection, 2 x 1.17 mL syringes

12301K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	0.00	395.12	25.00	Evenity [AN]

▪ROMOSOZUMAB

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

Severe established osteoporosis

Treatment Phase: Initial treatment - First-line therapy

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with any of: (i) anti-resorptive therapy, (ii) teriparatide, (iii) romosozumab, (iv) abaloparatide; **OR**
- Patient must have developed intolerance to abaloparatide of a severity necessitating permanent treatment withdrawal within the first 6 months of therapy, **AND**
- Patient must be at very high risk of fracture, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must have had a symptomatic fracture due to minimal trauma, **AND**
- Patient must have had at least 1 hip or symptomatic vertebral fracture in the previous 24 months; **OR**
- Patient must have had at least 2 fractures including 1 symptomatic new fracture in the previous 24 months, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must not exceed a lifetime maximum of 12 months of PBS and non-PBS-subsidised therapy.

Treatment criteria:

- Must be treated by a consultant physician.

Details of fracture history including the date(s), site(s), the symptoms associated with the fracture(s) and the score of the qualifying BMD measurement must be provided at the time of application.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Anti-resorptive therapies for osteoporosis include alendronate sodium, risedronate sodium, raloxifene hydrochloride, denosumab and zoledronic acid.

Authority Required

Severe established osteoporosis

Treatment Phase: Continuing treatment - First-line therapy

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition as first-line therapy, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must not exceed a lifetime maximum of 12 months of PBS and non-PBS-subsidised therapy.

Treatment criteria:

- Must be treated by a medical practitioner identifying as either: (i) a consultant physician, (ii) a general practitioner.

romosozumab 105 mg/1.17 mL injection, 2 x 1.17 mL syringes

14641N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	0.00	395.12	25.00	Evenity [AN]

▪SELPERCATINIB

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

Note Special Pricing Arrangements apply.

Authority Required (STREAMLINED)

19021

Advanced or metastatic medullary thyroid cancer

Clinical criteria:

- The condition must be unresectable with documented disease progression prior to commencing treatment with this drug, **AND**
- The condition must have evidence of activating RET variants in tumour material - this evidence has been obtained prior to commencing treatment with this drug, **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, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication, **AND**
- Patient must be initiating treatment with this drug; **OR**
- Patient must be continuing treatment with this drug, with an absence of further disease progression while being treated with this drug.

Medical practitioners must prescribe the appropriate quantities of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks per dispensing, according to the specified dosage in the approved Therapeutic Goods Administration (TGA) Product Information (PI). A separate authority prescription form must be completed for each strength requested.

Selpercatinib 40 mg tablet, 56

15447B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	0.00	2146.86	25.00	Retevmo [LY]

▪SELPERCATINIB

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 (STREAMLINED)

19048

Advanced or metastatic medullary thyroid cancer

Clinical criteria:

- The condition must be unresectable with documented disease progression prior to commencing treatment with this drug, **AND**
- The condition must have evidence of activating RET variants in tumour material - this evidence has been obtained prior to commencing treatment with this drug, **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, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication, **AND**
- Patient must be initiating treatment with this drug; **OR**
- Patient must be continuing treatment with this drug, with an absence of further disease progression while being treated with this drug.

Medical practitioners must prescribe the appropriate quantities of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks per dispensing, according to the specified dosage in the approved

Therapeutic Goods Administration (TGA) Product Information (PI). A separate authority prescription form must be completed for each strength requested.

Medical practitioners may prescribe selpercatinib 80 mg with a quantity of up to 56 units where the dose does not exceed 120 mg twice daily (i.e., in combination with selpercatinib 40 mg). Selpercatinib 80 mg with a quantity of 112 units must be prescribed only where the dose is 160 mg twice daily to provide 28 days of treatment per dispensing. Prescribers should refer to the TGA PI for dosing and dose adjustments regimens.

Selpercatinib 80 mg tablet, 56

15494L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	0.00	*8213.36	25.00	Retevmo [LY]

▪TERIPARATIDE

Note Pharmaceutical benefits that have the form teriparatide 250 microgram/mL injection, 2.4 mL cartridge and the pharmaceutical benefits that have the form teriparatide 250 microgram/mL injection, 2.4 mL pen device are equivalent for the purposes of substitution.

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

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

Authority Required (STREAMLINED)

19012

Severe established osteoporosis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist; **OR**
- Must be treated by a consultant physician.

Clinical criteria:

- Patient must be at very high risk of fracture, **AND**
- Patient must have a bone mineral density (BMD) T-score of -3.0 or less, **AND**
- Patient must have had 2 or more fractures due to minimal trauma, **AND**
- Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must not exceed a lifetime maximum of 18 months therapy, **AND**
- Patient must not have received PBS-subsidised treatment with any of: (i) romosozumab, (ii) abaloparatide; **OR**
- Patient must have developed intolerance to: (i) romosozumab, or (ii) abaloparatide of a severity necessitating permanent treatment withdrawal within the first 6 months of therapy.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months and zoledronic acid 5 mg per annum.

Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be documented in the patient's medical record.

Authority Required (STREAMLINED)

12270

Severe established osteoporosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- The treatment must not exceed a lifetime maximum of 18 months therapy.

Treatment criteria:

- Must be treated by a specialist; **OR**
- Must be treated by a consultant physician.

Note Up to a maximum of 18 pens will be reimbursed through the PBS.

teriparatide 250 microgram/mL injection, 2.4 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
14093R	1	5	0.00	173.14	25.00	[a] Teriparatide Lupin [GQ]	[a] Terrosa [FX]

teriparatide 250 microgram/mL injection, 2.4 mL cartridge

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
15152L	1	5	0.00	173.14	25.00	[a] Ritosa [XT]

▪TILDRAKIZUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

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

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

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

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

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

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

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

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

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

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

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

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

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

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

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

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

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

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

Note Special Pricing Arrangements apply.

Authority Required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the continuing treatment (whole body) restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the continuing treatment (face/hand/foot) restriction to complete 24 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a dermatologist.

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).

Tildrakizumab 100 mg/mL injection, 2 x 1 mL syringes

15448C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	0.00	6159.64	25.00	Ilumya [RA]

▪TILDRAKIZUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

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

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

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

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

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

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

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

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be

deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

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

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

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

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

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

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

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

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

Note Special Pricing Arrangements apply.

Authority Required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have both: (i) experienced an adequate response following the most recent course of treatment at the 100 mg dosage regimen and (ii) the treating physician determined that a more satisfactory response can be achieved at the 200 mg dosage regimen; **OR**
- Patient must have demonstrated an adequate response to the most recent course of treatment with this drug at the 200 mg dosage regimen, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

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

(a) details of the proposed prescription(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to not have responded to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient does not demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

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

Tildrakizumab 100 mg/mL injection, 2 x 1 mL syringes

15449D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	0.00	6159.64	25.00	Ilumya [RA]

▪ TILDRAKIZUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

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

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

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

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

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

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

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

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

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

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

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

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

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

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

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

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority Required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have both: (i) experienced an adequate response following the most recent course of treatment at the 100 mg dosage regimen and (ii) the treating physician determined that a more satisfactory response can be achieved at the 200 mg dosage regimen; **OR**
- Patient must have demonstrated an adequate response to the most recent course of treatment with this drug at the 200 mg dosage regimen, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

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

(a) details of the proposed prescription(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to not have responded to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient does not demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

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

Tildrakizumab 100 mg/mL injection, 2 x 1 mL syringes

15458N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	0.00	6159.64	25.00	Ilumya [RA]

▪VORASIDENIB

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 (STREAMLINED)

19016

Adult-type IDH-mutant astrocytoma or oligodendroglioma

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a World Health Organisation (WHO) Grade 2 astrocytoma or oligodendroglioma, **AND**
- Patient must have a test of tumour tissue confirming the presence of a susceptible isocitrate dehydrogenase-1 (IDH1) variant or isocitrate dehydrogenase-2 (IDH2) variant, **AND**
- Patient must have residual or recurrent disease after at least one prior surgery (biopsy, sub-total resection, or gross total resection) for this condition, **AND**
- Patient must not be in immediate need of radiotherapy and/or chemotherapy for this condition, **AND**
- The condition must not have been previously treated with systemic anticancer therapy or radiotherapy, **AND**
- Patient must have either a: (i) Karnofsky Performance Score of at least 80%, (ii) Lansky Performance Score of at least 80%.

Confirm that evidence of the presence of a susceptible IDH1 or IDH2 variant in the tumour tissue is documented/retained in the patient's medical records once only with the first PBS prescription.

Authority Required (STREAMLINED)

19035

Adult-type IDH-mutant astrocytoma or oligodendroglioma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Authority Required (STREAMLINED)

18999

Adult-type IDH-mutant astrocytoma or oligodendroglioma

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

Clinical criteria:

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 August 2026, **AND**
- Patient must have a World Health Organisation (WHO) Grade 2 astrocytoma or oligodendroglioma, **AND**
- Patient must have had a susceptible isocitrate dehydrogenase-1 (IDH1) mutation or isocitrate dehydrogenase-2 (IDH2) mutation at the time of initiation of non-PBS-subsidised treatment with this drug, **AND**
- Patient must have had an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1, at initiation of non-PBS-subsidised treatment with this drug, **AND**
- Patient must have had residual or recurrent disease after at least one prior surgery (biopsy, sub-total resection, or gross total resection) for this condition at the time of initiation of non-PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must not have been previously treated with systemic anticancer therapy prior to initiation of non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Confirm that evidence of the presence of a susceptible IDH1 or IDH2 variant in the tumour tissue is documented/retained in the patient's medical records once only with the first PBS prescription.

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

Vorasidenib 10 mg tablet, 30

15437L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	0.00	*28947.36	25.00	Voranigo [SE]

Vorasidenib 40 mg tablet, 30

15461R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	0.00	28724.36	25.00	Voranigo [SE]

Highly Specialised Drugs Program (Private Hospital)

▪ BUROSUMAB

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

Note Special Pricing Arrangements apply.

Authority Required

X-linked hypophosphataemia

Treatment Phase: Initial treatment - New patient

Clinical criteria:

- Patient must have a documented confirmation of PHEX pathogenic variant; **OR**
- Patient must have a confirmed diagnosis of X-linked hypophosphataemia demonstrated by the presence of all of the following: (i) a serum phosphate concentration below the age adjusted lower limit of normal; (ii) current or historical (for those with growth plate fusion) radiographic X-ray evidence of rickets; (iii) elevated (or inappropriately normal) serum or plasma FGF-23 levels of above the mean of the assay-specific reference range; (iv) renal phosphate wasting demonstrated by a ratio of tubular maximum reabsorption rate of phosphate to glomerular filtration rate (TmP/GFR) according to age specific normal ranges using the second morning urine void and paired serum sample measuring phosphate and creatinine.

Treatment criteria:

- Must be treated by a medical practitioner identifying as at least one of the following specialists: (i) paediatric endocrinologist, (ii) paediatric nephrologist, (iii) endocrinologist, (iv) nephrologist.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

Authority Required

X-linked hypophosphataemia

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved normalisation in serum phosphate levels; **OR**
- The condition must have been reviewed by a second specialist physician with expertise in the management of this condition, confirming that continuing therapy is clinically required, **AND**
- Patient must have radiographical evidence of stabilisation/improvement in rickets in patients without growth plate fusion.

Treatment criteria:

- Must be treated by a medical practitioner identifying as at least one of the following specialists: (i) paediatric endocrinologist, (ii) paediatric nephrologist, (iii) endocrinologist, (iv) nephrologist.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

burosumab 10 mg/mL injection, 1 mL vial

13163T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	4048.24	Crysvita [KO]

burosumab 20 mg/mL injection, 1 mL vial

13136J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	8047.24	Crysvita [KO]

burosumab 30 mg/mL injection, 1 mL vial

13154H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	12046.24	Crysvita [KO]

▪BUROSUMAB

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

Note Special Pricing Arrangements apply.

Authority Required

Tumour-induced osteomalacia

Treatment Phase: Initial treatment - New patient

Clinical criteria:

- Patient must have a confirmed diagnosis of hypophosphataemia in tumour-induced osteomalacia demonstrated by the presence of all of the following: (i) chronic clinical symptoms of fatigue, bone pain, muscle weakness and/or (pseudo) fractures; (ii) elevated (or inappropriately normal) serum or plasma FGF-23 levels above the mean of the assay-specific reference range; (iii) a serum phosphate concentration below the age adjusted lower limit of normal; (iv) renal phosphate wasting demonstrated by a ratio of tubular maximum reabsorption rate of phosphate to glomerular filtration rate (TmP/GFR) according to age specific normal ranges using the second morning urine void and paired serum sample measuring phosphate and creatinine, **AND**
- Patient must not be a candidate for curative surgical resection as a result of either: (i) inability to locate the causative tumour using all available functional imaging technologies; (ii) inability to completely resect the causative tumour due to size, anatomical location, or other patient contraindications or comorbidities; **OR**
- Patient must have demonstrated persistent hypophosphataemia despite complete surgical resection of the suspected causative tumour.

Treatment criteria:

- Must be treated by a medical practitioner identifying as at least one of the following specialists: (i) paediatric endocrinologist, (ii) paediatric nephrologist, (iii) endocrinologist, (iv) nephrologist.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

Prescribers should, where possible, rule out all other non-hereditary forms of FGF-23 related hypophosphataemia such as Fanconi syndrome, iron-infusion associated hypophosphataemia or post renal transplantation hypophosphataemia, prior to initiating patients on burosumab treatment for this condition.

Authority Required

Tumour-induced osteomalacia

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved normalisation in serum phosphate levels; **OR**
- The condition must have been reviewed by a second specialist physician with expertise in the management of this condition, confirming that continuing therapy is clinically required.

Treatment criteria:

- Must be treated by a medical practitioner identifying as at least one of the following specialists: (i) paediatric endocrinologist, (ii) paediatric nephrologist, (iii) endocrinologist, (iv) nephrologist.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

Authority Required

Tumour-induced osteomalacia

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

Clinical criteria:

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 August 2026, **AND**
- Patient must have, prior to initiating treatment with this drug, a confirmed diagnosis of hypophosphataemia in tumour-induced osteomalacia demonstrated by the presence of all of the following: (i) chronic clinical symptoms of fatigue, bone pain, muscle weakness and/or (pseudo) fractures; (ii) elevated (or inappropriately normal) serum or plasma FGF-23

levels above the mean of the assay-specific reference range; (iii) a serum phosphate concentration below the age adjusted lower limit of normal; (iv) renal phosphate wasting demonstrated by a ratio of tubular maximum reabsorption rate of phosphate to glomerular filtration rate (TmP/GFR) according to age specific normal ranges using the second morning urine void and paired serum sample measuring phosphate and creatinine, **AND**

- Patient must not have been a candidate for curative surgical resection, prior to initiating treatment with this drug, as a result of either: (i) inability to locate the causative tumour using all available functional imaging technologies; (ii) inability to completely resect the causative tumour due to size, anatomical location, or other patient contraindications or comorbidities; **OR**
- Patient must have had demonstrated persistent hypophosphataemia despite complete surgical resection of the suspected causative tumour prior to initiating treatment with this drug, **AND**
- Patient must have achieved normalisation in serum phosphate levels; **OR**
- The condition must have been reviewed by a second specialist physician with expertise in the management of this condition, confirming that continuing therapy is clinically required.

Treatment criteria:

- Must be treated by a medical practitioner identifying as at least one of the following specialists: (i) paediatric endocrinologist, (ii) paediatric nephrologist, (iii) endocrinologist, (iv) nephrologist.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

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

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

burosumab 10 mg/mL injection, 1 mL vial

15479Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	4048.24	Crysvita [KO]

burosumab 20 mg/mL injection, 1 mL vial

15500T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	8047.24	Crysvita [KO]

burosumab 30 mg/mL injection, 1 mL vial

15493K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	12046.24	Crysvita [KO]

▪CLOZAPINE

Note Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed.

Authority Required (STREAMLINED)

9490

Schizophrenia

Treatment Phase: Initial treatment

Treatment criteria:

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

Clinical criteria:

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

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

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

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

clozapine 25 mg tablet, 100

6101D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	0	0.00	*68.74	Clopine 25 [DU]	Clozaril 25 [GO]
					Clozitor [JU]	

clozapine 50 mg tablet, 100

6417R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	0	0.00	*124.66	Clopine 50 [DU]	Clozitor [JU]

clozapine 50 mg/mL oral liquid, 100 mL

9632Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	149.64	Clopine Suspension [DU]

clozapine 100 mg tablet, 100

6102E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	0	0.00	*225.64	Clopine 100 [DU]	Clozaril 100 [GO]
				Clozitor [JU]	

clozapine 200 mg tablet, 100

6418T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	0	0.00	*442.04	Clopine 200 [DU]	Clozitor [JU]

▪INFLIXIMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for 'severe Crohn disease' and infliximab for 'moderate to severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time or Initial 3 type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if 3 trials of a targeted therapy do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies. A paediatric patient cannot trial and not demonstrate an adequate response, or cease to respond to, the same PBS-subsidised targeted therapy more than twice.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

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

Treatment Phases:

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks for infliximab.

Initial 1 - use when the patient has never received a PBS-subsidised targeted therapy for these indications. Inadequate response to conventional therapy must be demonstrated where required.

Initial 2 - use when:

- an alternative targeted therapy is being prescribed for these indications; or
- the patient has previously been treated with this targeted therapy; or
- treatment is resuming after a break of less than 12 months

Patients applying through this treatment phase do not have to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Inadequate response to conventional therapy does not need to be redemonstrated.

Initial 3 - use when treatment is resuming after a break in PBS-subsidised treatment of at least 12 months. Patients applying through this treatment phase must requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Re-trial of conventional therapies is not required.

Continuing treatment - use when a patient has demonstrated an adequate response to the preceding supply. Patients are eligible for up to 24 weeks of treatment per continuing prescription. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Baseline measurements to determine response - a response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements provided in the first authority application for a targeted therapy. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recency of assessments:

Where possible, all related assessment documentation (including the Paediatric Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

Note Consistent with clinical guidelines, therapeutic drug monitoring is recommended during drug escalation/de-escalation to target trough medication levels

Note Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required (STREAMLINED)

19011

Moderate to severe Crohn disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must have both: (i) a total PCDAI score of 30 points or less, and (ii) a reduction in PCDAI score by at least 15 points from baseline value; **OR**
- Patient must have an adequate response to this drug defined as an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

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

If a patient does not demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition under this treatment phase. Patients may re-trial treatment with this drug under the 'Initial 2' treatment phase if eligible. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

An increase in the maximum quantity to allow for dosing of up to 10 mg per kg body weight will be authorised.

An increase in maximum repeats to 5 may be requested.

infliximab 100 mg injection, 1 vial

11450P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
5	2	0.00	*977.29	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remicade [JC]	[a] Remsima [EW]
				[a] Renflexis [OQ]	

▪INFLIXIMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for 'severe Crohn disease' and infliximab for 'moderate to severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time or Initial 3 type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if 3 trials of a targeted therapy do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies. A paediatric patient cannot trial and not demonstrate an adequate response, or cease to respond to, the same PBS-subsidised targeted therapy more than twice.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

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

Treatment Phases:

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks for infliximab.

Initial 1 - use when the patient has never received a PBS-subsidised targeted therapy for these indications. Inadequate response to conventional therapy must be demonstrated where required.

Initial 2 - use when:

- an alternative targeted therapy is being prescribed for these indications; or
- the patient has previously been treated with this targeted therapy; or
- treatment is resuming after a break of less than 12 months

Patients applying through this treatment phase do not have to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Inadequate response to conventional therapy does not need to be redemonstrated.

Initial 3 - use when treatment is resuming after a break in PBS-subsidised treatment of at least 12 months. Patients applying through this treatment phase must requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Re-trial of conventional therapies is not required.

Continuing treatment - use when a patient has demonstrated an adequate response to the preceding supply. Patients are eligible for up to 24 weeks of treatment per continuing prescription. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Baseline measurements to determine response - a response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements provided in the first authority application for a targeted therapy. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recency of assessments:

Where possible, all related assessment documentation (including the Paediatric Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Consistent with clinical guidelines, therapeutic drug monitoring is recommended during drug escalation/de-escalation to target trough medication levels

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 Authority applications for increased quantities/repeats may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

Authority Required

Moderate to severe Crohn disease

Treatment Phase: Initial 1 (new patient)

Clinical criteria:

- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must not have achieved an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy with a thiopurine at a clinically optimised dose, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; **OR**
- Patient must have a documented contraindication to each of prednisolone (or equivalent), a thiopurine, and methotrexate; **OR**
- Patient must have features of high-risk or complicated Crohn disease defined as those with any of the following: (i) perianal disease, (ii) stricturing or penetrating behaviour, (iii) severe delayed growth (growth velocity at least 2 standard deviations below the mean for age and sex, or a drop of at least 1 major centile band), **AND**
- Patient must have a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30; **OR**
- Patient must have extensive intestinal inflammation of the small intestine as evidenced by radiological imaging, **AND**
- Patient must not receive more than 12-14 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

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

(b) current PCDAI score and the date of assessment; or

(c) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

For patients assessed as having extensive intestinal inflammation of the small intestines, such evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant contraindications or precautions in the TGA-approved Product Information, please provide details at the time of application. Patients must attempt to trial alternate conventional therapies that are not contraindicated.

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

An increase in the maximum quantity to allow for dosing of up to 10 mg per kg body weight with 3 repeats will be authorised.

If fewer than 3 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

Where a response assessment is not conducted, the patient will be deemed to have not responded to treatment with this drug. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Authority Required

Moderate to severe Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must not have previously received this drug for this condition in this treatment cycle; **OR**
- Patient must have previously received this drug for this condition and demonstrated/maintained an adequate clinical response; **OR**
- Patient must have: (i) received this drug in this treatment cycle, (ii) not demonstrated/maintained an adequate response to this drug once in this treatment cycle, **AND**
- Patient must not receive more than 12-14 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, the PCDAI score and the date of assessment; or

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' clinical and treatment criteria when targeted therapy treatment commenced. The following information must also be provided at the time of application:

(a) the baseline PCDAI score and the date of assessment; or

(b) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

An increase in the maximum quantity to allow for dosing of up to 10 mg per kg body weight with 3 repeats will be authorised.

If fewer than 3 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

Where a response assessment is not conducted, the patient will be deemed to have not responded to treatment with this drug. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Authority Required

Moderate to severe Crohn disease

Treatment Phase: Initial 3 (recommencement of treatment after a break in targeted therapy of more than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition, **AND**

- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised targeted therapy for this condition, **AND**
- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must have a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 while off treatment with targeted therapy; **OR**
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease while off treatment with targeted therapy, **AND**
- Patient must not receive more than 12-14 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) current PCDAI score and the date of assessment; or

(b) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

For patients assessed as having extensive intestinal inflammation of the small intestines, such evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

An increase in the maximum quantity to allow for dosing of up to 10 mg per kg body weight with 3 repeats will be authorised.

If fewer than 3 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

Where a response assessment is not conducted, the patient will be deemed to have not responded to treatment with this drug. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Authority Required

Moderate to severe Crohn disease

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient treatment with this drug for this condition under any relevant initial restriction (Initial 1, 2 or 3), **AND**
- The treatment must provide no more than the balance of up to 14 weeks therapy available under Initial 1, 2 or 3 treatment.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

infliximab 100 mg injection, 1 vial

9612X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	202.85	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remicade [JC]	[a] Remsima [EW]
				[a] Renflexis [OQ]	

▪ LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed:

- Revlimid - i-access program;

- Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program;
- Lenalide - Juno Connected™;
- Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program.

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 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

Relapsed or refractory follicular lymphoma

Clinical criteria:

- The treatment must be in combination with rituximab and tafasitamab; **OR**
- The treatment must be in combination with tafasitamab.

The treatment must not exceed a total of 12 cycles in a lifetime for this indication measured from the initial dose, or must not extend beyond disease progression, whichever comes first.

lenalidomide 5 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
15418L	1	5	0.00	396.90	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 10 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
15485B	1	5	0.00	517.10	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 15 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
15488E	1	5	0.00	620.91	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 20 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
15486C	1	5	0.00	797.29	[a] Lenalide [JU]	[a] Lenalidomide Sandoz [SZ]

▪NITISINONE

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

Authority Required

Hereditary tyrosinaemia type 1 (HT-1)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a confirmed diagnosis of HT-1 based on the presence of succinylacetone in either: (i) urine, (ii) blood, **AND**
- The treatment must be in combination with dietary restriction of tyrosine and phenylalanine, **AND**
- Patient must not be suffering from any other severe or life-threatening medical condition, including complications or sequelae of HT-1, that might compromise the effectiveness of treatment with this drug or where the long-term prognosis is unlikely to be altered by treatment with this drug.

Treatment criteria:

- Must be treated by a physician with expertise in the management of HT-1, **AND**
- Must be treated in a centre with expertise in genetic metabolic disorders.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail.

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

(i) details of the proposed prescription; 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).

At the time of authority application, the prescriber must request the appropriate quantity units of appropriate strength(s), based on the weight of the patient, to provide sufficient drug for up to 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI). Up to 5 repeats will be authorised to provide for a total of 24 weeks of treatment.

A separate authority prescription form must be completed for each strength requested.

Confirmation of eligibility for treatment with diagnostic reports including the blood and/or urine test results must be conducted no more than 12 months prior to the date of authority application and documented in the patient's medical records.

Prescribers must state the patient's body weight with every authority application, and document it 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 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

Hereditary tyrosinaemia type 1 (HT-1)

Treatment Phase: Grandfather arrangement (transition from LSDP-funded Hereditary Tyrosinaemia type 1 therapy)

Clinical criteria:

- Patient must have previously received treatment with this drug for this condition under the Australian Government's Life Saving Drugs Program (LSDP) prior to 1 August 2026, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, the details of which must be kept with the patient's record, **AND**
- Patient must not have developed another life threatening/severe disease where long term prognosis is unlikely to be influenced by this drug, **AND**
- The treatment must be in combination with dietary restriction of tyrosine and phenylalanine.

Treatment criteria:

- Must be treated by a physician with expertise in the management of HT-1, **AND**
- Must be treated in a centre with expertise in genetic metabolic disorders.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail.

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

(i) details of the proposed prescription; 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).

At the time of authority application, the prescriber must request the appropriate quantity units of appropriate strength(s), based on the weight of the patient, to provide sufficient drug for up to 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI). Up to 5 repeats will be authorised to provide for a total of 24 weeks of treatment.

A separate authority prescription form must be completed for each strength requested.

Confirmation of eligibility for treatment with diagnostic reports including the blood and/or urine test results at baseline, must be documented in the patient's medical records.

Prescribers must state the patient's body weight with every authority application, and document it in the patient's medical records.

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

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

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

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

Applications for authorisation under this restriction should be made 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

Hereditary tyrosinaemia type 1 (HT-1)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, the details of which must be kept with the patient's record, **AND**

- Patient must not have developed another life threatening/severe disease where long term prognosis is unlikely to be influenced by this drug, **AND**
- The treatment must be in combination with dietary restriction of tyrosine and phenylalanine.

Treatment criteria:

- Must be treated by a physician with expertise in the management of HT-1, **AND**
- Must be treated in a centre with expertise in genetic metabolic disorders.

At the time of authority application, the prescriber must request the appropriate quantity units of appropriate strength(s), based on the weight of the patient, to provide sufficient drug for up to 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI). Up to 5 repeats will be authorised to provide for a total of 24 weeks of treatment.

A separate authority prescription form must be completed for each strength requested.

Liver function tests (LFT), Full blood count (FBC) and Alpha-fetoprotein (AFP) results confirming eligibility for continuing treatment must be documented in the patient's medical records.

Prescribers must state the patient's body weight with every authority application, and document it 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).

nitisinone 2 mg capsule, 60

15481T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	1218.15	Orfadin [FK]

nitisinone 5 mg capsule, 60

15425W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	2321.25	Orfadin [FK]

nitisinone 10 mg capsule, 60

15467C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	3995.62	Orfadin [FK]

nitisinone 20 mg capsule, 60

15459P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	7415.80	Orfadin [FK]

▪NITISINONE

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

Authority Required

Hereditary tyrosinaemia type 1 (HT-1)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a confirmed diagnosis of HT-1 based on the presence of succinylacetone in either: (i) urine, (ii) blood, **AND**
- The treatment must be in combination with dietary restriction of tyrosine and phenylalanine, **AND**
- Patient must not be suffering from any other severe or life-threatening medical condition, including complications or sequelae of HT-1, that might compromise the effectiveness of treatment with this drug or where the long-term prognosis is unlikely to be altered by treatment with this drug.

Treatment criteria:

- Must be treated by a physician with expertise in the management of HT-1, **AND**
- Must be treated in a centre with expertise in genetic metabolic disorders.

Population criteria:

- Patient must be less than 18 years of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail.

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

(i) details of the proposed prescription; 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).

At the time of authority application, the prescriber must request the appropriate quantity units of appropriate strength(s), based on the weight of the patient, to provide sufficient drug for up to 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI). Up to 5 repeats will be authorised to provide for a total of 24 weeks of treatment.

A separate authority prescription form must be completed for each strength requested.

Confirmation of eligibility for treatment with diagnostic reports including the blood and/or urine test results must be conducted no more than 12 months prior to the date of authority application and documented in the patient's medical records.

Prescribers must state the patient's body weight with every authority application, and document it 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 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

Hereditary tyrosinaemia type 1 (HT-1)

Treatment Phase: Grandfather arrangement (transition from LSDP-funded Hereditary Tyrosinaemia type 1 therapy)

Clinical criteria:

- Patient must have previously received treatment with this drug for this condition under the Australian Government's Life Saving Drugs Program (LSDP) prior to 1 August 2026, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, the details of which must be kept with the patient's record, **AND**
- Patient must not have developed another life threatening/severe disease where long term prognosis is unlikely to be influenced by this drug, **AND**
- The treatment must be in combination with dietary restriction of tyrosine and phenylalanine.

Treatment criteria:

- Must be treated by a physician with expertise in the management of HT-1, **AND**
- Must be treated in a centre with expertise in genetic metabolic disorders.

Population criteria:

- Patient must be less than 18 years of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail.

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

(i) details of the proposed prescription; 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).

At the time of authority application, the prescriber must request the appropriate quantity units of appropriate strength(s), based on the weight of the patient, to provide sufficient drug for up to 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI). Up to 5 repeats will be authorised to provide for a total of 24 weeks of treatment.

A separate authority prescription form must be completed for each strength requested.

Confirmation of eligibility for treatment with diagnostic reports including the blood and/or urine test results at baseline, must be documented in the patient's medical records.

Prescribers must state the patient's body weight with every authority application, and document it in the patient's medical records.

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

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

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

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

Applications for authorisation under this restriction should be made 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

Hereditary tyrosinaemia type 1 (HT-1)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, the details of which must be kept with the patient's record, **AND**
- Patient must not have developed another life threatening/severe disease where long term prognosis is unlikely to be influenced by this drug, **AND**
- The treatment must be in combination with dietary restriction of tyrosine and phenylalanine.

Treatment criteria:

- Must be treated by a physician with expertise in the management of HT-1, **AND**
- Must be treated in a centre with expertise in genetic metabolic disorders.

Population criteria:

- Patient must be less than 18 years of age.

At the time of authority application, the prescriber must request the appropriate quantity units of appropriate strength(s), based on the weight of the patient, to provide sufficient drug for up to 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI). Up to 5 repeats will be authorised to provide for a total of 24 weeks of treatment.

A separate authority prescription form must be completed for each strength requested.

Liver function tests (LFT), Full blood count (FBC) and Alpha-fetoprotein (AFP) results confirming eligibility for continuing treatment must be documented in the patient's medical records.

Prescribers must state the patient's body weight with every authority application, and document it 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).

nitisinone 4 mg/mL oral liquid, 90 mL

15502X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡1	5	0.00	4198.82	Orfadin [FK]

▪PEGUNIGALSIDASE ALFA

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

Note Special Pricing Arrangements apply.

Authority Required

Fabry disease

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have at least one of: (i) documented deficiency of alpha-galactosidase enzyme activity in blood, (ii) presence of genetic mutations known to result in deficiency of alpha-galactosidase enzyme activity, **AND**
- Patient must be male with Fabry-related renal disease confirmed by at least one of the following: (i) abnormal albuminuria of more than 20 mcg/min, as determined by 2 separate samples at least 24 hours apart, (ii) abnormal proteinuria of more than 150 mg/24 hours, (iii) albumin:creatinine ratio greater than upper limit of normal in 2 separate samples at least 24 hours apart, (iv) renal disease due to long-term accumulation of glycosphingolipids in the kidneys; **OR**
- Patient must be female with Fabry-related renal disease confirmed by at least one of the following: (i) proteinuria of more than 300 mg/24 hours with clinical evidence of progression, (ii) renal disease due to long-term accumulation of glycosphingolipids in the kidneys; **OR**
- Patient must have Fabry-related cardiac disease confirmed by at least one of the following: (i) left ventricular hypertrophy, as evidenced by cardiac magnetic resonance imaging (MRI) or echocardiogram data, in the absence of hypertension, (ii) significant life-threatening arrhythmia or conduction defect, (iii) late gadolinium enhancement or a low T1 on cardiac MRI; **OR**
- Patient must have Fabry-related either: (i) ischaemic disease, (ii) cerebrovascular disease as shown on objective testing with no other cause or risk factors identified; **OR**
- Patient must have Fabry-related uncontrolled chronic pain despite the use of recommended doses of appropriate analgesia and antiseizure medications for peripheral neuropathy; **OR**
- Patient must have significant Fabry-related gastrointestinal symptoms despite the use of the recommended doses of appropriate pharmacological therapies, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of Fabry disease.

If hypertension is present in patients relying their eligibility on Fabry-related cardiac disease, the prescriber must treat it optimally for at least 6 months prior to submitting the first PBS authority application.

Confirmation of eligibility for treatment with diagnostic reports including the confirmed mutations must be documented in the patient's medical records.

At the time of authority application, prescribers must request the appropriate number of vials, based on the weight of the patient, to provide sufficient drug for 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI).

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

(1) details of the proposed prescription(s); and

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

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 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

Fabry disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, the details of which must be kept with the patient's record, **AND**
- Patient must not have developed another life threatening/severe disease where long term prognosis is unlikely to be influenced by this drug, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of Fabry disease.

At the time of authority application, prescribers must request the appropriate number of vials, based on the weight of the patient, to provide sufficient drug for 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI).

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

Fabry disease

Treatment Phase: Grandfather arrangement (transition from LSDP-funded Fabry disease therapy)

Clinical criteria:

- Patient must have previously received treatment with Enzyme Replacement Therapy for this condition funded under the Australian Government's Life Saving Drugs Program (LSDP) prior to 1 August 2026, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of Fabry disease.

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

Confirmation of eligibility for treatment with diagnostic reports including the confirmed mutations must be documented in the patient's medical records.

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

(1) details of the proposed prescription(s); and

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

At the time of authority application, prescribers must request the appropriate number of vials, based on the weight of the patient, to provide sufficient drug for 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI).

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 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

Fabry disease

Treatment Phase: Switching from PBS-subsidised migalastat

Clinical criteria:

- Patient must have received prior treatment with PBS-subsidised migalastat for this condition, **AND**
- Patient must not have developed another life threatening/severe disease where long term prognosis is unlikely to be influenced by this drug, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have failed to demonstrate clinical improvement or stabilisation of this condition with previous PBS-subsidised treatment with this drug.

Treatment criteria:

- Must be treated by a physician with expertise in the management of Fabry disease.

Confirmation of eligibility for treatment with diagnostic reports including the confirmed mutations must be documented in the patient's medical records.

At the time of authority application, prescribers must request the appropriate number of vials, based on the weight of the patient, to provide sufficient drug for 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI).

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).

Pegunigalsidase alfa 20 mg/10 mL injection, 10 mL vial

15483X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	2891.64	ELFABRIO [EU]

▪ TEDUGLUTIDE

Note

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

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

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

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

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

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

Note Special Pricing Arrangements apply.

Authority Required

Type III Short bowel syndrome with intestinal failure

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a specialist within a multidisciplinary intestinal rehabilitation unit.

Clinical criteria:

- Patient must have short bowel syndrome with intestinal failure following major surgery, **AND**
- Patient must have a history of dependence on parenteral support for at least 12 months, **AND**
- Patient must have received a stable parenteral support regimen for at least 3 days per week in the 4 weeks prior to commencing this drug, **AND**
- Patient must not have active gastrointestinal malignancy or history of gastrointestinal malignancy within the last 5 years, **AND**
- The treatment must not exceed 12 months under this restriction, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

Provide a baseline value in this authority application of the amount of parenteral support per week, expressed as either:
(i) for a patient of any age, the mean number of days of parenteral support per week,

(ii) for a patient yet to turn 18 years of age, the mean volume of parenteral support per week in mL per kg.

Determine the mean over any given 4 week period prior to commencing this drug. For a patient yet to turn 18 years of age, both (i) and (ii) may be supplied, but provide at least (i).

Assessment of treatment response/non-response in the 'Continuing treatment' authority application will be compared against the baseline value(s) submitted in this application.

A stable parenteral support regimen is defined as a minimum of 3 days of parenteral support (parenteral nutrition with or without IV fluids) per week for 4 consecutive weeks to meet caloric, fluid or electrolyte needs.

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

(a) details of the proposed prescription(s); 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).

teduglutide 5 mg injection [28 vials] (&) inert substance diluent [28 x 0.5 mL syringes], 1 pack

11795T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	11	0.00	19759.84	Revestive [TK]

Highly Specialised Drugs Program (Public Hospital)

▪ BUROSUMAB

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

Note Special Pricing Arrangements apply.

Authority Required

X-linked hypophosphataemia

Treatment Phase: Initial treatment - New patient

Clinical criteria:

- Patient must have a documented confirmation of PHEX pathogenic variant; **OR**
- Patient must have a confirmed diagnosis of X-linked hypophosphataemia demonstrated by the presence of all of the following: (i) a serum phosphate concentration below the age adjusted lower limit of normal; (ii) current or historical (for those with growth plate fusion) radiographic X-ray evidence of rickets; (iii) elevated (or inappropriately normal) serum or plasma FGF-23 levels of above the mean of the assay-specific reference range; (iv) renal phosphate wasting demonstrated by a ratio of tubular maximum reabsorption rate of phosphate to glomerular filtration rate (TmP/GFR) according to age specific normal ranges using the second morning urine void and paired serum sample measuring phosphate and creatinine.

Treatment criteria:

- Must be treated by a medical practitioner identifying as at least one of the following specialists: (i) paediatric endocrinologist, (ii) paediatric nephrologist, (iii) endocrinologist, (iv) nephrologist.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

Authority Required

X-linked hypophosphataemia

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved normalisation in serum phosphate levels; **OR**
- The condition must have been reviewed by a second specialist physician with expertise in the management of this condition, confirming that continuing therapy is clinically required, **AND**
- Patient must have radiographical evidence of stabilisation/improvement in rickets in patients without growth plate fusion.

Treatment criteria:

- Must be treated by a medical practitioner identifying as at least one of the following specialists: (i) paediatric endocrinologist, (ii) paediatric nephrologist, (iii) endocrinologist, (iv) nephrologist.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

burosumab 10 mg/mL injection, 1 mL vial

13140N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	3999.00	Crysvita [KO]

burosumab 20 mg/mL injection, 1 mL vial

13145W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	7998.00	Crysvita [KO]

burosumab 30 mg/mL injection, 1 mL vial

13155J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	11997.00	Crysvita [KO]

▪BUROSUMAB

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

Note Special Pricing Arrangements apply.

Authority Required

Tumour-induced osteomalacia

Treatment Phase: Initial treatment - New patient

Clinical criteria:

- Patient must have a confirmed diagnosis of hypophosphataemia in tumour-induced osteomalacia demonstrated by the presence of all of the following: (i) chronic clinical symptoms of fatigue, bone pain, muscle weakness and/or (pseudo) fractures; (ii) elevated (or inappropriately normal) serum or plasma FGF-23 levels above the mean of the assay-specific reference range; (iii) a serum phosphate concentration below the age adjusted lower limit of normal; (iv) renal phosphate wasting demonstrated by a ratio of tubular maximum reabsorption rate of phosphate to glomerular filtration rate (TmP/GFR) according to age specific normal ranges using the second morning urine void and paired serum sample measuring phosphate and creatinine, **AND**
- Patient must not be a candidate for curative surgical resection as a result of either: (i) inability to locate the causative tumour using all available functional imaging technologies; (ii) inability to completely resect the causative tumour due to size, anatomical location, or other patient contraindications or comorbidities; **OR**
- Patient must have demonstrated persistent hypophosphataemia despite complete surgical resection of the suspected causative tumour.

Treatment criteria:

- Must be treated by a medical practitioner identifying as at least one of the following specialists: (i) paediatric endocrinologist, (ii) paediatric nephrologist, (iii) endocrinologist, (iv) nephrologist.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

Prescribers should, where possible, rule out all other non-hereditary forms of FGF-23 related hypophosphataemia such as Fanconi syndrome, iron-infusion associated hypophosphataemia or post renal transplantation hypophosphataemia, prior to initiating patients on burosumab treatment for this condition.

Authority Required

Tumour-induced osteomalacia

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved normalisation in serum phosphate levels; **OR**
- The condition must have been reviewed by a second specialist physician with expertise in the management of this condition, confirming that continuing therapy is clinically required.

Treatment criteria:

- Must be treated by a medical practitioner identifying as at least one of the following specialists: (i) paediatric endocrinologist, (ii) paediatric nephrologist, (iii) endocrinologist, (iv) nephrologist.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

Authority Required

Tumour-induced osteomalacia

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

Clinical criteria:

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 August 2026, **AND**
- Patient must have, prior to initiating treatment with this drug, a confirmed diagnosis of hypophosphataemia in tumour-induced osteomalacia demonstrated by the presence of all of the following: (i) chronic clinical symptoms of fatigue, bone pain, muscle weakness and/or (pseudo) fractures; (ii) elevated (or inappropriately normal) serum or plasma FGF-23

levels above the mean of the assay-specific reference range; (iii) a serum phosphate concentration below the age adjusted lower limit of normal; (iv) renal phosphate wasting demonstrated by a ratio of tubular maximum reabsorption rate of phosphate to glomerular filtration rate (TmP/GFR) according to age specific normal ranges using the second morning urine void and paired serum sample measuring phosphate and creatinine, **AND**

- Patient must not have been a candidate for curative surgical resection, prior to initiating treatment with this drug, as a result of either: (i) inability to locate the causative tumour using all available functional imaging technologies; (ii) inability to completely resect the causative tumour due to size, anatomical location, or other patient contraindications or comorbidities; **OR**
- Patient must have had demonstrated persistent hypophosphataemia despite complete surgical resection of the suspected causative tumour prior to initiating treatment with this drug, **AND**
- Patient must have achieved normalisation in serum phosphate levels; **OR**
- The condition must have been reviewed by a second specialist physician with expertise in the management of this condition, confirming that continuing therapy is clinically required.

Treatment criteria:

- Must be treated by a medical practitioner identifying as at least one of the following specialists: (i) paediatric endocrinologist, (ii) paediatric nephrologist, (iii) endocrinologist, (iv) nephrologist.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

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

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

burosumab 10 mg/mL injection, 1 mL vial

15422Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	3999.00	Crysvita [KO]

burosumab 20 mg/mL injection, 1 mL vial

15434H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	7998.00	Crysvita [KO]

burosumab 30 mg/mL injection, 1 mL vial

15480R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	11997.00	Crysvita [KO]

▪CLOZAPINE

Note Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed.

Authority Required (STREAMLINED)

5015

Schizophrenia

Treatment Phase: Initial treatment

Treatment criteria:

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

Clinical criteria:

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

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

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

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

clozapine 25 mg tablet, 100

5628F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	0	0.00	*55.50	Clopine 25 [DU]	Clozaril 25 [GO]
				Clozitor [JU]	

clozapine 50 mg tablet, 100

5626D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	0	0.00	*110.98	Clopine 50 [DU]	Clozitor [JU]

clozapine 50 mg/mL oral liquid, 100 mL

5630H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	135.00	Clopine Suspension [DU]

clozapine 100 mg tablet, 100

5629G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	0	0.00	*208.08	Clopine 100 [DU]	Clozaril 100 [GO]
				Clozitor [JU]	

clozapine 200 mg tablet, 100

5627E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	0	0.00	*416.16	Clopine 200 [DU]	Clozitor [JU]

▪INFLIXIMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for 'severe Crohn disease' and infliximab for 'moderate to severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time or Initial 3 type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if 3 trials of a targeted therapy do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies. A paediatric patient cannot trial and not demonstrate an adequate response, or cease to respond to, the same PBS-subsidised targeted therapy more than twice.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

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

Treatment Phases:

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks for infliximab.

Initial 1 - use when the patient has never received a PBS-subsidised targeted therapy for these indications. Inadequate response to conventional therapy must be demonstrated where required.

Initial 2 - use when:

- an alternative targeted therapy is being prescribed for these indications; or
- the patient has previously been treated with this targeted therapy; or
- treatment is resuming after a break of less than 12 months

Patients applying through this treatment phase do not have to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Inadequate response to conventional therapy does not need to be redemonstrated.

Initial 3 - use when treatment is resuming after a break in PBS-subsidised treatment of at least 12 months. Patients applying through this treatment phase must requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Re-trial of conventional therapies is not required.

Continuing treatment - use when a patient has demonstrated an adequate response to the preceding supply. Patients are eligible for up to 24 weeks of treatment per continuing prescription. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Baseline measurements to determine response - a response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements provided in the first authority application for a targeted therapy. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recency of assessments:

Where possible, all related assessment documentation (including the Paediatric Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

Note Consistent with clinical guidelines, therapeutic drug monitoring is recommended during drug escalation/de-escalation to target trough medication levels

Note Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required (STREAMLINED)

19042

Moderate to severe Crohn disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must have both: (i) a total PCDAI score of 30 points or less, and (ii) a reduction in PCDAI score by at least 15 points from baseline value; **OR**
- Patient must have an adequate response to this drug defined as an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

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

If a patient does not demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition under this treatment phase. Patients may re-trial treatment with this drug under the 'Initial 2' treatment phase if eligible. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

An increase in the maximum quantity to allow for dosing of up to 10 mg per kg body weight will be authorised.

An increase in maximum repeats to 5 may be requested.

infliximab 100 mg injection, 1 vial

11449N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
5	2	0.00	*930.80	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remicade [JC]	[a] Remsima [EW]
				[a] Renflexis [OQ]	

▪INFLIXIMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for 'severe Crohn disease' and infliximab for 'moderate to severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time or Initial 3 type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if 3 trials of a targeted therapy do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies. A paediatric patient cannot trial and not demonstrate an adequate response, or cease to respond to, the same PBS-subsidised targeted therapy more than twice.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

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

Treatment Phases:

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks for infliximab.

Initial 1 - use when the patient has never received a PBS-subsidised targeted therapy for these indications. Inadequate response to conventional therapy must be demonstrated where required.

Initial 2 - use when:

- an alternative targeted therapy is being prescribed for these indications; or
- the patient has previously been treated with this targeted therapy; or
- treatment is resuming after a break of less than 12 months

Patients applying through this treatment phase do not have to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Inadequate response to conventional therapy does not need to be redemonstrated.

Initial 3 - use when treatment is resuming after a break in PBS-subsidised treatment of at least 12 months. Patients applying through this treatment phase must requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Re-trial of conventional therapies is not required.

Continuing treatment - use when a patient has demonstrated an adequate response to the preceding supply. Patients are eligible for up to 24 weeks of treatment per continuing prescription. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Baseline measurements to determine response - a response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements provided in the first authority application for a targeted therapy. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recency of assessments:

Where possible, all related assessment documentation (including the Paediatric Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Consistent with clinical guidelines, therapeutic drug monitoring is recommended during drug escalation/de-escalation to target trough medication levels

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 Authority applications for increased quantities/repeats may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

Authority Required

Moderate to severe Crohn disease

Treatment Phase: Initial 1 (new patient)

Clinical criteria:

- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must not have achieved an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy with a thiopurine at a clinically optimised dose, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; **OR**
- Patient must have a documented contraindication to each of prednisolone (or equivalent), a thiopurine, and methotrexate; **OR**
- Patient must have features of high-risk or complicated Crohn disease defined as those with any of the following: (i) perianal disease, (ii) stricturing or penetrating behaviour, (iii) severe delayed growth (growth velocity at least 2 standard deviations below the mean for age and sex, or a drop of at least 1 major centile band), **AND**
- Patient must have a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30; **OR**
- Patient must have extensive intestinal inflammation of the small intestine as evidenced by radiological imaging, **AND**
- Patient must not receive more than 12-14 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

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

(b) current PCDAI score and the date of assessment; or

(c) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

For patients assessed as having extensive intestinal inflammation of the small intestines, such evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant contraindications or precautions in the TGA-approved Product Information, please provide details at the time of application. Patients must attempt to trial alternate conventional therapies that are not contraindicated.

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

An increase in the maximum quantity to allow for dosing of up to 10 mg per kg body weight with 3 repeats will be authorised.

If fewer than 3 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

Where a response assessment is not conducted, the patient will be deemed to have not responded to treatment with this drug. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Authority Required

Moderate to severe Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must not have previously received this drug for this condition in this treatment cycle; **OR**
- Patient must have previously received this drug for this condition and demonstrated/maintained an adequate clinical response; **OR**
- Patient must have: (i) received this drug in this treatment cycle, (ii) not demonstrated/maintained an adequate response to this drug once in this treatment cycle, **AND**
- Patient must not receive more than 12-14 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, the PCDAI score and the date of assessment; or

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' clinical and treatment criteria when targeted therapy treatment commenced. The following information must also be provided at the time of application:

(a) the baseline PCDAI score and the date of assessment; or

(b) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

An increase in the maximum quantity to allow for dosing of up to 10 mg per kg body weight with 3 repeats will be authorised.

If fewer than 3 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

Where a response assessment is not conducted, the patient will be deemed to have not responded to treatment with this drug. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Authority Required

Moderate to severe Crohn disease

Treatment Phase: Initial 3 (recommencement of treatment after a break in targeted therapy of more than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition, **AND**

- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised targeted therapy for this condition, **AND**
- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must have a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 while off treatment with targeted therapy; **OR**
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease while off treatment with targeted therapy, **AND**
- Patient must not receive more than 12-14 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) current PCDAI score and the date of assessment; or

(b) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

For patients assessed as having extensive intestinal inflammation of the small intestines, such evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

An increase in the maximum quantity to allow for dosing of up to 10 mg per kg body weight with 3 repeats will be authorised.

If fewer than 3 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

Where a response assessment is not conducted, the patient will be deemed to have not responded to treatment with this drug. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Authority Required

Moderate to severe Crohn disease

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient treatment with this drug for this condition under any relevant initial restriction (Initial 1, 2 or 3), **AND**
- The treatment must provide no more than the balance of up to 14 weeks therapy available under Initial 1, 2 or 3 treatment.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

infliximab 100 mg injection, 1 vial

5755X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	186.16	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remicade [JC]	[a] Remsima [EW]
				[a] Renflexis [OQ]	

▪ LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed:

- Revlimid - i-access program;

- Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program;
- Lenalide - Juno Connected™;
- Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program.

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 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

Relapsed or refractory follicular lymphoma

Clinical criteria:

- The treatment must be in combination with rituximab and tafasitamab; **OR**
- The treatment must be in combination with tafasitamab.

The treatment must not exceed a total of 12 cycles in a lifetime for this indication measured from the initial dose, or must not extend beyond disease progression, whichever comes first.

lenalidomide 5 mg capsule, 21

15487D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	372.75	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 10 mg capsule, 21

15451F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	488.33	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 15 mg capsule, 21

15452G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	588.14	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 20 mg capsule, 21

15428B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	757.74	[a] Lenalide [JU]	[a] Lenalidomide Sandoz [SZ]

▪NITISINONE

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

Authority Required

Hereditary tyrosinaemia type 1 (HT-1)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a confirmed diagnosis of HT-1 based on the presence of succinylacetone in either: (i) urine, (ii) blood, **AND**
- The treatment must be in combination with dietary restriction of tyrosine and phenylalanine, **AND**
- Patient must not be suffering from any other severe or life-threatening medical condition, including complications or sequelae of HT-1, that might compromise the effectiveness of treatment with this drug or where the long-term prognosis is unlikely to be altered by treatment with this drug.

Treatment criteria:

- Must be treated by a physician with expertise in the management of HT-1, **AND**
- Must be treated in a centre with expertise in genetic metabolic disorders.

Population criteria:

- Patient must be less than 18 years of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail.

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

(i) details of the proposed prescription; 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).

At the time of authority application, the prescriber must request the appropriate quantity units of appropriate strength(s), based on the weight of the patient, to provide sufficient drug for up to 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI). Up to 5 repeats will be authorised to provide for a total of 24 weeks of treatment.

A separate authority prescription form must be completed for each strength requested.

Confirmation of eligibility for treatment with diagnostic reports including the blood and/or urine test results must be conducted no more than 12 months prior to the date of authority application and documented in the patient's medical records.

Prescribers must state the patient's body weight with every authority application, and document it 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 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

Hereditary tyrosinaemia type 1 (HT-1)

Treatment Phase: Grandfather arrangement (transition from LSDP-funded Hereditary Tyrosinaemia type 1 therapy)

Clinical criteria:

- Patient must have previously received treatment with this drug for this condition under the Australian Government's Life Saving Drugs Program (LSDP) prior to 1 August 2026, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, the details of which must be kept with the patient's record, **AND**
- Patient must not have developed another life threatening/severe disease where long term prognosis is unlikely to be influenced by this drug, **AND**
- The treatment must be in combination with dietary restriction of tyrosine and phenylalanine.

Treatment criteria:

- Must be treated by a physician with expertise in the management of HT-1, **AND**
- Must be treated in a centre with expertise in genetic metabolic disorders.

Population criteria:

- Patient must be less than 18 years of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail.

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

(i) details of the proposed prescription; 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).

At the time of authority application, the prescriber must request the appropriate quantity units of appropriate strength(s), based on the weight of the patient, to provide sufficient drug for up to 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI). Up to 5 repeats will be authorised to provide for a total of 24 weeks of treatment.

A separate authority prescription form must be completed for each strength requested.

Confirmation of eligibility for treatment with diagnostic reports including the blood and/or urine test results at baseline, must be documented in the patient's medical records.

Prescribers must state the patient's body weight with every authority application, and document it in the patient's medical records.

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

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

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

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

Applications for authorisation under this restriction should be made 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

Hereditary tyrosinaemia type 1 (HT-1)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, the details of which must be kept with the patient's record, **AND**
- Patient must not have developed another life threatening/severe disease where long term prognosis is unlikely to be influenced by this drug, **AND**
- The treatment must be in combination with dietary restriction of tyrosine and phenylalanine.

Treatment criteria:

- Must be treated by a physician with expertise in the management of HT-1, **AND**
- Must be treated in a centre with expertise in genetic metabolic disorders.

Population criteria:

- Patient must be less than 18 years of age.

At the time of authority application, the prescriber must request the appropriate quantity units of appropriate strength(s), based on the weight of the patient, to provide sufficient drug for up to 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI). Up to 5 repeats will be authorised to provide for a total of 24 weeks of treatment.

A separate authority prescription form must be completed for each strength requested.

Liver function tests (LFT), Full blood count (FBC) and Alpha-fetoprotein (AFP) results confirming eligibility for continuing treatment must be documented in the patient's medical records.

Prescribers must state the patient's body weight with every authority application, and document it 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).

nitisinone 4 mg/mL oral liquid, 90 mL

15426X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡1	5	0.00	4149.58	Orfadin [FK]

▪NITISINONE

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

Authority Required

Hereditary tyrosinaemia type 1 (HT-1)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a confirmed diagnosis of HT-1 based on the presence of succinylacetone in either: (i) urine, (ii) blood, **AND**
- The treatment must be in combination with dietary restriction of tyrosine and phenylalanine, **AND**
- Patient must not be suffering from any other severe or life-threatening medical condition, including complications or sequelae of HT-1, that might compromise the effectiveness of treatment with this drug or where the long-term prognosis is unlikely to be altered by treatment with this drug.

Treatment criteria:

- Must be treated by a physician with expertise in the management of HT-1, **AND**
- Must be treated in a centre with expertise in genetic metabolic disorders.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail.

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

(i) details of the proposed prescription; 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).

At the time of authority application, the prescriber must request the appropriate quantity units of appropriate strength(s), based on the weight of the patient, to provide sufficient drug for up to 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI). Up to 5 repeats will be authorised to provide for a total of 24 weeks of treatment.

A separate authority prescription form must be completed for each strength requested.

Confirmation of eligibility for treatment with diagnostic reports including the blood and/or urine test results must be conducted no more than 12 months prior to the date of authority application and documented in the patient's medical records.

Prescribers must state the patient's body weight with every authority application, and document it 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 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

Hereditary tyrosinaemia type 1 (HT-1)

Treatment Phase: Grandfather arrangement (transition from LSDP-funded Hereditary Tyrosinaemia type 1 therapy)

Clinical criteria:

- Patient must have previously received treatment with this drug for this condition under the Australian Government's Life Saving Drugs Program (LSDP) prior to 1 August 2026, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, the details of which must be kept with the patient's record, **AND**
- Patient must not have developed another life threatening/severe disease where long term prognosis is unlikely to be influenced by this drug, **AND**
- The treatment must be in combination with dietary restriction of tyrosine and phenylalanine.

Treatment criteria:

- Must be treated by a physician with expertise in the management of HT-1, **AND**
- Must be treated in a centre with expertise in genetic metabolic disorders.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail.

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

(i) details of the proposed prescription; 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).

At the time of authority application, the prescriber must request the appropriate quantity units of appropriate strength(s), based on the weight of the patient, to provide sufficient drug for up to 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI). Up to 5 repeats will be authorised to provide for a total of 24 weeks of treatment.

A separate authority prescription form must be completed for each strength requested.

Confirmation of eligibility for treatment with diagnostic reports including the blood and/or urine test results at baseline, must be documented in the patient's medical records.

Prescribers must state the patient's body weight with every authority application, and document it in the patient's medical records.

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

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

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

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

Applications for authorisation under this restriction should be made 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

Hereditary tyrosinaemia type 1 (HT-1)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, the details of which must be kept with the patient's record, **AND**
- Patient must not have developed another life threatening/severe disease where long term prognosis is unlikely to be influenced by this drug, **AND**
- The treatment must be in combination with dietary restriction of tyrosine and phenylalanine.

Treatment criteria:

- Must be treated by a physician with expertise in the management of HT-1, **AND**
- Must be treated in a centre with expertise in genetic metabolic disorders.

At the time of authority application, the prescriber must request the appropriate quantity units of appropriate strength(s), based on the weight of the patient, to provide sufficient drug for up to 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI). Up to 5 repeats will be authorised to provide for a total of 24 weeks of treatment.

A separate authority prescription form must be completed for each strength requested.

Liver function tests (LFT), Full blood count (FBC) and Alpha-fetoprotein (AFP) results confirming eligibility for continuing treatment must be documented in the patient's medical records.

Prescribers must state the patient's body weight with every authority application, and document it 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).

nitisinone 2 mg capsule, 60

15482W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	1168.91	Orfadin [FK]

nitisinone 5 mg capsule, 60

15460Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	2272.01	Orfadin [FK]

nitisinone 10 mg capsule, 60

15435J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	3946.38	Orfadin [FK]

nitisinone 20 mg capsule, 60

15501W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	7366.56	Orfadin [FK]

▪ PEGUNIGALSIDASE ALFA

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

Note Special Pricing Arrangements apply.

Authority Required

Fabry disease

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have at least one of: (i) documented deficiency of alpha-galactosidase enzyme activity in blood, (ii) presence of genetic mutations known to result in deficiency of alpha-galactosidase enzyme activity, **AND**
- Patient must be male with Fabry-related renal disease confirmed by at least one of the following: (i) abnormal albuminuria of more than 20 mcg/min, as determined by 2 separate samples at least 24 hours apart, (ii) abnormal proteinuria of more than 150 mg/24 hours, (iii) albumin:creatinine ratio greater than upper limit of normal in 2 separate samples at least 24 hours apart, (iv) renal disease due to long-term accumulation of glycosphingolipids in the kidneys; **OR**
- Patient must be female with Fabry-related renal disease confirmed by at least one of the following: (i) proteinuria of more than 300 mg/24 hours with clinical evidence of progression, (ii) renal disease due to long-term accumulation of glycosphingolipids in the kidneys; **OR**
- Patient must have Fabry-related cardiac disease confirmed by at least one of the following: (i) left ventricular hypertrophy, as evidenced by cardiac magnetic resonance imaging (MRI) or echocardiogram data, in the absence of hypertension, (ii) significant life-threatening arrhythmia or conduction defect, (iii) late gadolinium enhancement or a low T1 on cardiac MRI; **OR**
- Patient must have Fabry-related either: (i) ischaemic disease, (ii) cerebrovascular disease as shown on objective testing with no other cause or risk factors identified; **OR**
- Patient must have Fabry-related uncontrolled chronic pain despite the use of recommended doses of appropriate analgesia and antiseizure medications for peripheral neuropathy; **OR**
- Patient must have significant Fabry-related gastrointestinal symptoms despite the use of the recommended doses of appropriate pharmacological therapies, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of Fabry disease.

If hypertension is present in patients relying their eligibility on Fabry-related cardiac disease, the prescriber must treat it optimally for at least 6 months prior to submitting the first PBS authority application.

Confirmation of eligibility for treatment with diagnostic reports including the confirmed mutations must be documented in the patient's medical records.

At the time of authority application, prescribers must request the appropriate number of vials, based on the weight of the patient, to provide sufficient drug for 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI).

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

(1) details of the proposed prescription(s); and

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

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 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

Fabry disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, the details of which must be kept with the patient's record, **AND**
- Patient must not have developed another life threatening/severe disease where long term prognosis is unlikely to be influenced by this drug, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of Fabry disease.

At the time of authority application, prescribers must request the appropriate number of vials, based on the weight of the patient, to provide sufficient drug for 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI).

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

Fabry disease

Treatment Phase: Grandfather arrangement (transition from LSDP-funded Fabry disease therapy)

Clinical criteria:

- Patient must have previously received treatment with Enzyme Replacement Therapy for this condition funded under the Australian Government's Life Saving Drugs Program (LSDP) prior to 1 August 2026, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of Fabry disease.

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

Confirmation of eligibility for treatment with diagnostic reports including the confirmed mutations must be documented in the patient's medical records.

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

(1) details of the proposed prescription(s); and

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

At the time of authority application, prescribers must request the appropriate number of vials, based on the weight of the patient, to provide sufficient drug for 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI).

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 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

Fabry disease

Treatment Phase: Switching from PBS-subsidised migalastat

Clinical criteria:

- Patient must have received prior treatment with PBS-subsidised migalastat for this condition, **AND**
- Patient must not have developed another life threatening/severe disease where long term prognosis is unlikely to be influenced by this drug, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have failed to demonstrate clinical improvement or stabilisation of this condition with previous PBS-subsidised treatment with this drug.

Treatment criteria:

- Must be treated by a physician with expertise in the management of Fabry disease.

Confirmation of eligibility for treatment with diagnostic reports including the confirmed mutations must be documented in the patient's medical records.

At the time of authority application, prescribers must request the appropriate number of vials, based on the weight of the patient, to provide sufficient drug for 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI).

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).

Pegunigalsidase alfa 20 mg/10 mL injection, 10 mL vial

15469E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	2842.40	ELFABRIO [EU]

▪ TEDUGLUTIDE

Note

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

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

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

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

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

Note Special Pricing Arrangements apply.

Authority Required

Type III Short bowel syndrome with intestinal failure

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a specialist within a multidisciplinary intestinal rehabilitation unit.

Clinical criteria:

- Patient must have short bowel syndrome with intestinal failure following major surgery, **AND**
- Patient must have a history of dependence on parenteral support for at least 12 months, **AND**
- Patient must have received a stable parenteral support regimen for at least 3 days per week in the 4 weeks prior to commencing this drug, **AND**
- Patient must not have active gastrointestinal malignancy or history of gastrointestinal malignancy within the last 5 years, **AND**
- The treatment must not exceed 12 months under this restriction, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

Provide a baseline value in this authority application of the amount of parenteral support per week, expressed as either:

(i) for a patient of any age, the mean number of days of parenteral support per week,

(ii) for a patient yet to turn 18 years of age, the mean volume of parenteral support per week in mL per kg.

Determine the mean over any given 4 week period prior to commencing this drug. For a patient yet to turn 18 years of age, both (i) and (ii) may be supplied, but provide at least (i).

Assessment of treatment response/non-response in the 'Continuing treatment' authority application will be compared against the baseline value(s) submitted in this application.

A stable parenteral support regimen is defined as a minimum of 3 days of parenteral support (parenteral nutrition with or without IV fluids) per week for 4 consecutive weeks to meet caloric, fluid or electrolyte needs.

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

(a) details of the proposed prescription(s); 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).

teduglutide 5 mg injection [28 vials] (&) inert substance diluent [28 x 0.5 mL syringes], 1 pack

11793Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	11	0.00	19710.60	Revestive [TK]

Highly Specialised Drugs Program (Community Access)

▪CLOZAPINE

Note Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed.

Authority Required (STREAMLINED)

4998

Schizophrenia

Treatment Phase: Continuing treatment

Treatment criteria:

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

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy with this drug for this condition, **AND**
- Patient must have completed at least 18 weeks therapy, **AND**
- Patient must be on a clozapine dosage considered stable by a treating psychiatrist, **AND**
- The treatment must be under the supervision and direction of a psychiatrist reviewing the patient at regular intervals.

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

clozapine 25 mg tablet, 100

10289M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	0	0.00	*71.12	25.00	Clopine 25 [DU] Clozitor [JU]	Clozaril 25 [GO]

clozapine 50 mg tablet, 100

10302F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	0	0.00	*129.64	25.00	Clopine 50 [DU]	Clozitor [JU]

clozapine 50 mg/mL oral liquid, 100 mL

10341G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	0	0.00	155.68	25.00	Clopine Suspension [DU]

clozapine 100 mg tablet, 100

10358E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	0	0.00	*234.94	25.00	Clopine 100 [DU] Clozitor [JU]	Clozaril 100 [GO]

clozapine 200 mg tablet, 100

10288L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	0	0.00	*460.66	25.00	Clopine 200 [DU]	Clozitor [JU]