Australian Government
Department of Health and Aged Care

PBS

Schedule of Pharmaceutical Benefits

Summary of Changes

Effective 1 December 2024

Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 December 2024 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	$8.67
	Dangerous drug fee	$5.37
	Extemporaneously-prepared	$10.71
	Allowable additional patient charge*	$3.45
Additional Fees (for safety net prices):	Ready-prepared	$1.45
	Extemporaneously-prepared	$1.87
Patient Co-payments:	General	$31.60
	Concessional	$7.70
Safety Net Thresholds:	General	$1647.90
	Concessional	$277.20
Safety Net Card Issue Fee:		$12.04

* 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 December 2024. The Schedule is updated on the first day of each month and is available on the internet at www.pbs.gov.au.

General Pharmaceutical Benefits

Additions

Addition – Item

14665W **BELZUTIFAN**, belzutifan 40 mg tablet, 90 *(Welireg)*

14671E **CARBAMAZEPINE**, carbamazepine 200 mg modified release tablet, 100 *(Tegretol CR 200)*

14673G **CARBAMAZEPINE**, carbamazepine 200 mg modified release tablet, 100 *(Tegretol CR 200)*

14681Q **CARBAMAZEPINE**, carbamazepine 200 mg modified release tablet, 100 *(Tegretol CR 200)*

14662Q **CARBAMAZEPINE**, carbamazepine 400 mg modified release tablet, 100 *(Tegretol CR 400)*

14666X **CARBAMAZEPINE**, carbamazepine 400 mg modified release tablet, 100 *(Tegretol CR 400)*

14680P **CARBAMAZEPINE**, carbamazepine 400 mg modified release tablet, 100 *(Tegretol CR 400)*

14675J **CLONAZEPAM**, clonazepam 2 mg tablet, 100 *(Clonazepam USP (Advagen Pharma, USA))*

14667Y **DIENOGEST**, dienogest 2 mg tablet, 28 *(Visanne)*

14668B **EZETIMIBE**, ezetimibe 10 mg tablet, 90 *(Ezetimibe USP (Camber, USA))*

14682R **EZETIMIBE**, ezetimibe 10 mg tablet, 90 *(Ezetimibe USP (Camber, USA))*

Addition – Brand

2698B *Abiraterone-Teva, TB* – **ABIRATERONE**, abiraterone acetate 250 mg tablet, 120

11206T *Abiraterone-Teva, TB* – **ABIRATERONE**, abiraterone acetate 500 mg tablet, 60

8300W *ATOVACUE, JM* – **ATOVAQUONE**, atovaquone 750 mg/5 mL oral liquid, 210 mL

13901P *Dostamine, NB* – **CABERGOLINE**, cabergoline 500 microgram tablet, 8

8114C *Dostamine, NB* – **CABERGOLINE**, cabergoline 500 microgram tablet, 8

12849G *Dasatinib Sandoz, SZ* – **DASATINIB**, dasatinib 20 mg tablet, 60

12850H *Dasatinib Sandoz, SZ* – **DASATINIB**, dasatinib 20 mg tablet, 60

12869H *Dasatinib Sandoz, SZ* – **DASATINIB**, dasatinib 20 mg tablet, 60

12888H *Dasatinib Sandoz, SZ* – **DASATINIB**, dasatinib 20 mg tablet, 60

1354G *Dasatinib Sandoz, SZ* – **DASATINIB**, dasatinib 20 mg tablet, 60

2478K *Dasatinib Sandoz, SZ* – **DASATINIB**, dasatinib 20 mg tablet, 60

9125G *Dasatinib Sandoz, SZ* – **DASATINIB**, dasatinib 20 mg tablet, 60

12843Y *Dasatinib Sandoz, SZ* – **DASATINIB**, dasatinib 50 mg tablet, 60

12857Q *Dasatinib Sandoz, SZ* – **DASATINIB**, dasatinib 50 mg tablet, 60

12860W *Dasatinib Sandoz, SZ* – **DASATINIB**, dasatinib 50 mg tablet, 60

12865D *Dasatinib Sandoz, SZ* – **DASATINIB**, dasatinib 50 mg tablet, 60

1381Q *Dasatinib Sandoz, SZ* – **DASATINIB**, dasatinib 50 mg tablet, 60

2482P *Dasatinib Sandoz, SZ* – **DASATINIB**, dasatinib 50 mg tablet, 60

9126H *Dasatinib Sandoz, SZ* – **DASATINIB**, dasatinib 50 mg tablet, 60

12866E *Dasatinib Sandoz, SZ* – **DASATINIB**, dasatinib 70 mg tablet, 60

12886F *Dasatinib Sandoz, SZ* – **DASATINIB**, dasatinib 70 mg tablet, 60

12890K *Dasatinib Sandoz, SZ* – **DASATINIB**, dasatinib 70 mg tablet, 60

12903D *Dasatinib Sandoz, SZ* – **DASATINIB**, dasatinib 70 mg tablet, 60

1415L *Dasatinib Sandoz, SZ* – **DASATINIB**, dasatinib 70 mg tablet, 60

2485T *Dasatinib Sandoz, SZ* – **DASATINIB**, dasatinib 70 mg tablet, 60

9127J *Dasatinib Sandoz, SZ* – **DASATINIB**, dasatinib 70 mg tablet, 60

12842X *Dasatinib Sandoz, SZ* – **DASATINIB**, dasatinib 100 mg tablet, 30

12859T *Dasatinib Sandoz, SZ* – **DASATINIB**, dasatinib 100 mg tablet, 30

12889J *Dasatinib Sandoz, SZ* – **DASATINIB**, dasatinib 100 mg tablet, 30

12902C *Dasatinib Sandoz, SZ* – **DASATINIB**, dasatinib 100 mg tablet, 30

1416M *Dasatinib Sandoz, SZ* – **DASATINIB**, dasatinib 100 mg tablet, 30

9342Q *Dasatinib Sandoz, SZ* – **DASATINIB**, dasatinib 100 mg tablet, 30

9343R *Dasatinib Sandoz, SZ* – **DASATINIB**, dasatinib 100 mg tablet, 30

13929D *Dutasteride/Tamsulosin Lupin 500/400, GQ* – **DUTASTERIDE + TAMSULOSIN**, dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram modified release capsule, 30

5490Y *Dutasteride/Tamsulosin Lupin 500/400, GQ* – **DUTASTERIDE + TAMSULOSIN**, dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram modified release capsule, 30

8559L *APX-GABAPENTIN, TX* – **GABAPENTIN**, gabapentin 600 mg tablet, 100

3190X *WGR-IBUPROFEN 400, WG* – **IBUPROFEN**, ibuprofen 400 mg tablet, 30

3192B *WGR-IBUPROFEN 400, WG* – **IBUPROFEN**, ibuprofen 400 mg tablet, 30

5123P *WGR-IBUPROFEN 400, WG* – **IBUPROFEN**, ibuprofen 400 mg tablet, 30

5124Q *WGR-IBUPROFEN 400, WG* – **IBUPROFEN**, ibuprofen 400 mg tablet, 30

11784F *Imanib, AF* – **IMATINIB**, imatinib 100 mg tablet, 60

11784F *Imatinib Sandoz, SZ* – **IMATINIB**, imatinib 100 mg tablet, 60

11787J *Imanib, AF* – **IMATINIB**, imatinib 100 mg tablet, 60

11787J *Imatinib Sandoz, SZ* – **IMATINIB**, imatinib 100 mg tablet, 60

5443L *Imanib, AF* – **IMATINIB**, imatinib 100 mg tablet, 60

5443L *Imatinib Sandoz, SZ* – **IMATINIB**, imatinib 100 mg tablet, 60

9111M *Imanib, AF* – **IMATINIB**, imatinib 100 mg tablet, 60

9111M *Imatinib Sandoz, SZ* – **IMATINIB**, imatinib 100 mg tablet, 60

11778X *Imanib, AF* – **IMATINIB**, imatinib 400 mg tablet, 30

11778X *Imatinib Sandoz, SZ* – **IMATINIB**, imatinib 400 mg tablet, 30

11788K *Imanib, AF* – **IMATINIB**, imatinib 400 mg tablet, 30

11788K *Imatinib Sandoz, SZ* – **IMATINIB**, imatinib 400 mg tablet, 30

5444M *Imanib, AF* – **IMATINIB**, imatinib 400 mg tablet, 30

5444M *Imatinib Sandoz, SZ* – **IMATINIB**, imatinib 400 mg tablet, 30

9112N *Imanib, AF* – **IMATINIB**, imatinib 400 mg tablet, 30

9112N *Imatinib Sandoz, SZ* – **IMATINIB**, imatinib 400 mg tablet, 30

13976N *Diaformin Viatris, MQ* – **METFORMIN**, metformin hydrochloride 500 mg tablet, 100

2430X *Diaformin Viatris, MQ* – **METFORMIN**, metformin hydrochloride 500 mg tablet, 100

14056T *METFORMIN-WGR, WG* – **METFORMIN**, metformin hydrochloride 1 g tablet, 90

8607B *METFORMIN-WGR, WG* – **METFORMIN**, metformin hydrochloride 1 g tablet, 90

1609Q *METHADONE-AFT, AE* – **METHADONE**, methadone hydrochloride 10 mg tablet, 20

13943W *APO-OLMESARTAN/AMLODIPINE 40/10, TY* – **OLMESARTAN + AMLODIPINE**, olmesartan medoxomil 40 mg + amlodipine 10 mg tablet, 30

5294P *APO-OLMESARTAN/AMLODIPINE 40/10, TY* – **OLMESARTAN + AMLODIPINE**, olmesartan medoxomil 40 mg + amlodipine 10 mg tablet, 30

14057W *ARX-PIOGLITAZONE, XT* – **PIOGLITAZONE**, pioglitazone 45 mg tablet, 28

8696Q *ARX-PIOGLITAZONE, XT* – **PIOGLITAZONE**, pioglitazone 45 mg tablet, 28

12192Q *RIVOXA, CR* – **RIVAROXABAN**, rivaroxaban 2.5 mg tablet, 60

12197Y *RIVOXA, CR* – **RIVAROXABAN**, rivaroxaban 2.5 mg tablet, 60

13366L *RIVOXA, CR* – **RIVAROXABAN**, rivaroxaban 2.5 mg tablet, 60

11633G *Rivaroxaban Sandoz, SZ* – **RIVAROXABAN**, rivaroxaban 10 mg tablet, 30

11633G *Rivoxa, CR* – **RIVAROXABAN**, rivaroxaban 10 mg tablet, 30

13521P *Rivaroxaban Sandoz, SZ* – **RIVAROXABAN**, rivaroxaban 10 mg tablet, 30

13521P *Rivoxa, CR* – **RIVAROXABAN**, rivaroxaban 10 mg tablet, 30

9467G *Rivaroxaban Sandoz, SZ* – **RIVAROXABAN**, rivaroxaban 10 mg tablet, 30

9467G *Rivoxa, CR* – **RIVAROXABAN**, rivaroxaban 10 mg tablet, 30

13463N *Rivaroxaban Sandoz, SZ* – **RIVAROXABAN**, rivaroxaban 15 mg tablet, 28

13463N *Rivoxa, CR* – **RIVAROXABAN**, rivaroxaban 15 mg tablet, 28

2160Q *Rivaroxaban Sandoz, SZ* – **RIVAROXABAN**, rivaroxaban 15 mg tablet, 42

2160Q *Rivoxa, CR* – **RIVAROXABAN**, rivaroxaban 15 mg tablet, 42

2691P *Rivaroxaban Sandoz, SZ* – **RIVAROXABAN**, rivaroxaban 15 mg tablet, 28

2691P *Rivoxa, CR* – **RIVAROXABAN**, rivaroxaban 15 mg tablet, 28

13462M *Rivaroxaban Sandoz, SZ* – **RIVAROXABAN**, rivaroxaban 20 mg tablet, 28

13462M *Rivoxa, CR* – **RIVAROXABAN**, rivaroxaban 20 mg tablet, 28

2268J *Rivaroxaban Sandoz, SZ* – **RIVAROXABAN**, rivaroxaban 20 mg tablet, 28

2268J *Rivoxa, CR* – **RIVAROXABAN**, rivaroxaban 20 mg tablet, 28

10551H *APO-RIZATRIPTAN ODT, TW* – **RIZATRIPTAN**, rizatriptan 10 mg orally disintegrating tablet, 2

3130R *Vancomycin Viatris, AL* – **VANCOMYCIN**, vancomycin 500 mg injection, 1 vial

3131T *Vancomycin Viatris, AL* – **VANCOMYCIN**, vancomycin 500 mg injection, 1 vial

3323X *Vancomycin Viatris, AL* – **VANCOMYCIN**, vancomycin 500 mg injection, 1 vial

2269K *Vancomycin Viatris, AL* – **VANCOMYCIN**, vancomycin 1 g injection, 1 vial

2270L *Vancomycin Viatris, AL* – **VANCOMYCIN**, vancomycin 1 g injection, 1 vial

5083M *Vancomycin Viatris, AL* – **VANCOMYCIN**, vancomycin 1 g injection, 1 vial

5469W *Varenicline Sandoz, SZ* – **VARENICLINE**, varenicline 1 mg tablet, 56

9129L *Varenicline Sandoz, SZ* – **VARENICLINE**, varenicline 1 mg tablet, 56

9128K *Varenicline Sandoz, SZ* – **VARENICLINE**, varenicline 500 microgram tablet [11] (&) varenicline 1 mg tablet [42], 53

Addition – Equivalence Indicator

2698B *Zytiga, JC* – **ABIRATERONE**, abiraterone acetate 250 mg tablet, 120

11206T *Zytiga, JC* – **ABIRATERONE**, abiraterone acetate 500 mg tablet, 60

8300W *Wellvone, AS* – **ATOVAQUONE**, atovaquone 750 mg/5 mL oral liquid, 210 mL

13901P *Dostinex, PF* – **CABERGOLINE**, cabergoline 500 microgram tablet, 8

8114C *Dostinex, PF* – **CABERGOLINE**, cabergoline 500 microgram tablet, 8

14050L *Tegretol CR 200, NV* – **CARBAMAZEPINE**, carbamazepine 200 mg modified release tablet, 200

2426Q *Tegretol CR 200, NV* – **CARBAMAZEPINE**, carbamazepine 200 mg modified release tablet, 200

5038E *Tegretol CR 200, NV* – **CARBAMAZEPINE**, carbamazepine 200 mg modified release tablet, 200

13918M *Tegretol CR 400, NV* – **CARBAMAZEPINE**, carbamazepine 400 mg modified release tablet, 200

2431Y *Tegretol CR 400, NV* – **CARBAMAZEPINE**, carbamazepine 400 mg modified release tablet, 200

5037D *Tegretol CR 400, NV* – **CARBAMAZEPINE**, carbamazepine 400 mg modified release tablet, 200

1806C *Paxam 2, AF* – **CLONAZEPAM**, clonazepam 2 mg tablet, 100

1609Q *Physeptone, AS* – **METHADONE**, methadone hydrochloride 10 mg tablet, 20

Addition – Note

14438X **BUDESONIDE**, budesonide 500 microgram/2 mL inhalation solution, 30 x 2 mL ampoules *(Pulmicort Respules)*

2065Q **BUDESONIDE**, budesonide 500 microgram/2 mL inhalation solution, 30 x 2 mL ampoules *(Pulmicort Respules)*

14469M **BUDESONIDE**, budesonide 1 mg/2 mL inhalation solution, 30 x 2 mL ampoules *(Pulmicort Respules)*

2066R **BUDESONIDE**, budesonide 1 mg/2 mL inhalation solution, 30 x 2 mL ampoules *(Pulmicort Respules)*

14050L **CARBAMAZEPINE**, carbamazepine 200 mg modified release tablet, 200 *(Tegretol CR 200)*

2426Q **CARBAMAZEPINE**, carbamazepine 200 mg modified release tablet, 200 *(Tegretol CR 200)*

5038E **CARBAMAZEPINE**, carbamazepine 200 mg modified release tablet, 200 *(Tegretol CR 200)*

13918M **CARBAMAZEPINE**, carbamazepine 400 mg modified release tablet, 200 *(Tegretol CR 400)*

2431Y **CARBAMAZEPINE**, carbamazepine 400 mg modified release tablet, 200 *(Tegretol CR 400)*

5037D **CARBAMAZEPINE**, carbamazepine 400 mg modified release tablet, 200 *(Tegretol CR 400)*

1806C **CLONAZEPAM**, clonazepam 2 mg tablet, 100 *(Paxam 2)*

13440J **EZETIMIBE**, ezetimibe 10 mg tablet, 30 *(APO-Ezetimibe, BTC Ezetimibe, EZEMICHOL, EZETIMIBE-WGR, Ezetimibe GH, Ezetimibe Sandoz, Ezetrol, Pharmacor Ezetimibe 10, Zient 10mg)*

8757X **EZETIMIBE**, ezetimibe 10 mg tablet, 30 *(APO-Ezetimibe, BTC Ezetimibe, EZEMICHOL, EZETIMIBE-WGR, Ezetimibe GH, Ezetimibe Sandoz, Ezetrol, Pharmacor Ezetimibe 10, Zient 10mg)*

10378F **TESTOSTERONE**, testosterone 5% (50 mg/mL) cream, 50 mL *(AndroForte 5)*

14563L **TESTOSTERONE**, testosterone 5% (50 mg/mL) cream, 50 mL *(AndroForte 5)*

Addition – Restriction

10011X **DAPAGLIFLOZIN**, dapagliflozin 10 mg tablet, 28 *(Forxiga)*

13844P **DAPAGLIFLOZIN**, dapagliflozin 10 mg tablet, 28 *(Forxiga)*

10510E **DAPAGLIFLOZIN + METFORMIN**, dapagliflozin 5 mg + metformin hydrochloride 1 g modified release tablet, 56 *(Xigduo XR 5/1000)*

13851B **DAPAGLIFLOZIN + METFORMIN**, dapagliflozin 5 mg + metformin hydrochloride 1 g modified release tablet, 56 *(Xigduo XR 5/1000)*

10516L **DAPAGLIFLOZIN + METFORMIN**, dapagliflozin 10 mg + metformin hydrochloride 500 mg modified release tablet, 28 *(Xigduo XR 10/500)*

14028H **DAPAGLIFLOZIN + METFORMIN**, dapagliflozin 10 mg + metformin hydrochloride 500 mg modified release tablet, 28 *(Xigduo XR 10/500)*

10515K **DAPAGLIFLOZIN + METFORMIN**, dapagliflozin 10 mg + metformin hydrochloride 1 g modified release tablet, 28 *(Xigduo XR 10/1000)*

13875G **DAPAGLIFLOZIN + METFORMIN**, dapagliflozin 10 mg + metformin hydrochloride 1 g modified release tablet, 28 *(Xigduo XR 10/1000)*

Deletions

Deletion – Item

8315P **CEFEPIME**, cefepime 1 g injection, 1 vial *(Cefepime Kabi)*

8316Q **CEFEPIME**, cefepime 2 g injection, 1 vial *(Cefepime Kabi)*

13347L **COLESTYRAMINE**, colestyramine 4 g powder for oral liquid, 30 sachets *(Cholestyramine-Odan)*

13351Q **COLESTYRAMINE**, colestyramine 4 g powder for oral liquid, 30 sachets *(Cholestyramine-Odan)*

3118D **MEDROXYPROGESTERONE**, medroxyprogesterone acetate 150 mg/mL injection, 1 mL vial *(Depo-Provera)*

14108M **PROCHLORPERAZINE**, prochlorperazine maleate 5 mg tablet, 250 *(Stemetil (Ireland))*

14129P **PROCHLORPERAZINE**, prochlorperazine maleate 5 mg tablet, 250 *(Stemetil (Ireland))*

Deletion – Brand

1590Q *Oruvail SR, AV* – **KETOPROFEN**, ketoprofen 200 mg modified release capsule, 28

5136H *Oruvail SR, AV* – **KETOPROFEN**, ketoprofen 200 mg modified release capsule, 28

3130R *Vancomycin Alphapharm, AF* – **VANCOMYCIN**, vancomycin 500 mg injection, 1 vial

3131T *Vancomycin Alphapharm, AF* – **VANCOMYCIN**, vancomycin 500 mg injection, 1 vial

3323X *Vancomycin Alphapharm, AF* – **VANCOMYCIN**, vancomycin 500 mg injection, 1 vial

2269K *Vancomycin Alphapharm, AF* – **VANCOMYCIN**, vancomycin 1 g injection, 1 vial

2270L *Vancomycin Alphapharm, AF* – **VANCOMYCIN**, vancomycin 1 g injection, 1 vial

5083M *Vancomycin Alphapharm, AF* – **VANCOMYCIN**, vancomycin 1 g injection, 1 vial

Deletion – Equivalence Indicator

1590Q *Orudis SR 200, SW* – **KETOPROFEN**, ketoprofen 200 mg modified release capsule, 28

5136H *Orudis SR 200, SW* – **KETOPROFEN**, ketoprofen 200 mg modified release capsule, 28

14160G *Depo-Provera, PF* – **MEDROXYPROGESTERONE**, medroxyprogesterone acetate 150 mg/mL injection, 1 mL syringe

Deletion – Note

2698B **ABIRATERONE**, abiraterone acetate 250 mg tablet, 120 *(Abiraterone-Teva, Zytiga)*

11206T **ABIRATERONE**, abiraterone acetate 500 mg tablet, 60 *(Abiraterone-Teva, Zytiga)*

14407G **APOMORPHINE**, apomorphine hydrochloride hemihydrate 50 mg/5 mL injection, 5 x 5 mL ampoules *(Movapo)*

14375N **APOMORPHINE**, apomorphine hydrochloride hemihydrate 100 mg/20 mL injection, 5 x 20 mL vials *(Apomine Solution for Infusion)*

14377Q **APOMORPHINE**, apomorphine hydrochloride hemihydrate 50 mg/10 mL injection, 5 x 10 mL syringes *(Movapo PFS)*

11484K **EVOLOCUMAB**, evolocumab 140 mg/mL injection, 1 mL pen device *(Repatha)*

11985T **EVOLOCUMAB**, evolocumab 140 mg/mL injection, 1 mL pen device *(Repatha)*

14160G **MEDROXYPROGESTERONE**, medroxyprogesterone acetate 150 mg/mL injection, 1 mL syringe *(Depo-Provera)*

2893G **PROCHLORPERAZINE**, prochlorperazine maleate 5 mg tablet, 25 *(APO-Prochlorperazine, PROCHLORPERAZINE-WGR, ProCalm, Prochlorperazine GH, Stemetil)*

5205Y **PROCHLORPERAZINE**, prochlorperazine maleate 5 mg tablet, 25 *(APO-Prochlorperazine, PROCHLORPERAZINE-WGR, ProCalm, Prochlorperazine GH, Stemetil)*

13768P **UPADACITINIB**, upadacitinib 15 mg modified release tablet, 28 *(Rinvoq)*

13746L **UPADACITINIB**, upadacitinib 30 mg modified release tablet, 28 *(Rinvoq)*

13771T **UPADACITINIB**, upadacitinib 45 mg modified release tablet, 28 *(Rinvoq)*

Deletion – Restriction

13768P **UPADACITINIB**, upadacitinib 15 mg modified release tablet, 28 *(Rinvoq)*

13746L **UPADACITINIB**, upadacitinib 30 mg modified release tablet, 28 *(Rinvoq)*

13771T **UPADACITINIB**, upadacitinib 45 mg modified release tablet, 28 *(Rinvoq)*

Alterations

Alteration – Note

14309D **APOMORPHINE**, apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL cartridges *(Apomine Intermittent)*

14485J **APOMORPHINE**, apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL pen devices *(Movapo Pen)*

10011X **DAPAGLIFLOZIN**, dapagliflozin 10 mg tablet, 28 *(Forxiga)*

13844P **DAPAGLIFLOZIN**, dapagliflozin 10 mg tablet, 28 *(Forxiga)*

10510E **DAPAGLIFLOZIN + METFORMIN**, dapagliflozin 5 mg + metformin hydrochloride 1 g modified release tablet, 56 *(Xigduo XR 5/1000)*

13851B **DAPAGLIFLOZIN + METFORMIN**, dapagliflozin 5 mg + metformin hydrochloride 1 g modified release tablet, 56 *(Xigduo XR 5/1000)*

10516L **DAPAGLIFLOZIN + METFORMIN**, dapagliflozin 10 mg + metformin hydrochloride 500 mg modified release tablet, 28 *(Xigduo XR 10/500)*

14028H **DAPAGLIFLOZIN + METFORMIN**, dapagliflozin 10 mg + metformin hydrochloride 500 mg modified release tablet, 28 *(Xigduo XR 10/500)*

10515K **DAPAGLIFLOZIN + METFORMIN**, dapagliflozin 10 mg + metformin hydrochloride 1 g modified release tablet, 28 *(Xigduo XR 10/1000)*

13875G **DAPAGLIFLOZIN + METFORMIN**, dapagliflozin 10 mg + metformin hydrochloride 1 g modified release tablet, 28 *(Xigduo XR 10/1000)*

11884L **LISDEXAMFETAMINE**, lisdexamfetamine dimesilate 20 mg capsule, 30 *(Vyvanse)*

10486X **LISDEXAMFETAMINE**, lisdexamfetamine dimesilate 30 mg capsule, 30 *(Vyvanse)*

11898F **LISDEXAMFETAMINE**, lisdexamfetamine dimesilate 40 mg capsule, 30 *(Vyvanse)*

10474G **LISDEXAMFETAMINE**, lisdexamfetamine dimesilate 50 mg capsule, 30 *(Vyvanse)*

11897E **LISDEXAMFETAMINE**, lisdexamfetamine dimesilate 60 mg capsule, 30 *(Vyvanse)*

10492F **LISDEXAMFETAMINE**, lisdexamfetamine dimesilate 70 mg capsule, 30 *(Vyvanse)*

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

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

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

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

12116Q **METHYLPHENIDATE**, methylphenidate hydrochloride 60 mg modified release capsule, 30 *(Ritalin LA, Rubifen LA)*

2387P **METHYLPHENIDATE**, methylphenidate hydrochloride 18 mg modified release tablet, 30 *(Concerta, METHYLPHENIDATE-TEVA XR, Methylphenidate XR ARX)*

2172H **METHYLPHENIDATE**, methylphenidate hydrochloride 27 mg modified release tablet, 30 *(Concerta, METHYLPHENIDATE-TEVA XR, Methylphenidate XR ARX)*

2388Q **METHYLPHENIDATE**, methylphenidate hydrochloride 36 mg modified release tablet, 30 *(Concerta, METHYLPHENIDATE-TEVA XR, Methylphenidate XR ARX)*

2432B **METHYLPHENIDATE**, methylphenidate hydrochloride 54 mg modified release tablet, 30 *(Concerta, METHYLPHENIDATE-TEVA XR, Methylphenidate XR ARX)*

Alteration – Restriction

11884L **LISDEXAMFETAMINE**, lisdexamfetamine dimesilate 20 mg capsule, 30 *(Vyvanse)*

10486X **LISDEXAMFETAMINE**, lisdexamfetamine dimesilate 30 mg capsule, 30 *(Vyvanse)*

11898F **LISDEXAMFETAMINE**, lisdexamfetamine dimesilate 40 mg capsule, 30 *(Vyvanse)*

10474G **LISDEXAMFETAMINE**, lisdexamfetamine dimesilate 50 mg capsule, 30 *(Vyvanse)*

11897E **LISDEXAMFETAMINE**, lisdexamfetamine dimesilate 60 mg capsule, 30 *(Vyvanse)*

10492F **LISDEXAMFETAMINE**, lisdexamfetamine dimesilate 70 mg capsule, 30 *(Vyvanse)*

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

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

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

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

12116Q **METHYLPHENIDATE**, methylphenidate hydrochloride 60 mg modified release capsule, 30 *(Ritalin LA, Rubifen LA)*

2387P **METHYLPHENIDATE**, methylphenidate hydrochloride 18 mg modified release tablet, 30 *(Concerta, METHYLPHENIDATE-TEVA XR, Methylphenidate XR ARX)*

2172H **METHYLPHENIDATE**, methylphenidate hydrochloride 27 mg modified release tablet, 30 *(Concerta, METHYLPHENIDATE-TEVA XR, Methylphenidate XR ARX)*

2388Q **METHYLPHENIDATE**, methylphenidate hydrochloride 36 mg modified release tablet, 30 *(Concerta, METHYLPHENIDATE-TEVA XR, Methylphenidate XR ARX)*

2432B **METHYLPHENIDATE**, methylphenidate hydrochloride 54 mg modified release tablet, 30 *(Concerta, METHYLPHENIDATE-TEVA XR, Methylphenidate XR ARX)*

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

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

10378F **TESTOSTERONE**, testosterone 5% (50 mg/mL) cream, 50 mL *(AndroForte 5)*

14563L **TESTOSTERONE**, testosterone 5% (50 mg/mL) cream, 50 mL *(AndroForte 5)*

Alteration – Manufacturer Code

		From	*To*
13081L	*Inqovi 35/100* – **DECITABINE + CEDAZURIDINE**, decitabine 35 mg + cedazuridine 100 mg tablet, 5	OS	TJ
13087T	*Inqovi 35/100* – **DECITABINE + CEDAZURIDINE**, decitabine 35 mg + cedazuridine 100 mg tablet, 5	OS	TJ
13107W	*Inqovi 35/100* – **DECITABINE + CEDAZURIDINE**, decitabine 35 mg + cedazuridine 100 mg tablet, 5	OS	TJ
13133F	*Inqovi 35/100* – **DECITABINE + CEDAZURIDINE**, decitabine 35 mg + cedazuridine 100 mg tablet, 5	OS	TJ

Supply Only

When a product is deleted from the Schedule it may be available under Supply Only rules. Supply Only items/brands are available on the Schedule for dispensing but not for prescribing, usually for a period of up to 12 months from when it is deleted. Substitution of Supply Only items/brands with products flagged as “equivalent for substitution” still apply as specified in the Schedule at the time the script was written.
Further information on Supply Only arrangements is available at https://www.pbs.gov.au/browse/medicine-listing/supply-only

5507W **CARMELLOSE SODIUM**, carmellose sodium 0.5% eye drops, 15 mL *(Refresh Tears Plus)*

8548X **CARMELLOSE SODIUM**, carmellose sodium 0.5% eye drops, 15 mL *(Refresh Tears Plus)*

9211T **CARMELLOSE SODIUM**, carmellose sodium 0.5% eye drops, 15 mL *(Refresh Tears Plus)*

5508X **CARMELLOSE SODIUM**, carmellose sodium 1% eye drops, 15 mL *(Refresh Liquigel)*

8593G **CARMELLOSE SODIUM**, carmellose sodium 1% eye drops, 15 mL *(Refresh Liquigel)*

9212W **CARMELLOSE SODIUM**, carmellose sodium 1% eye drops, 15 mL *(Refresh Liquigel)*

5556K **CARMELLOSE SODIUM + GLYCEROL**, carmellose sodium 0.5% + glycerol 0.9% eye drops, 15 mL *(Optive)*

9355J **CARMELLOSE SODIUM + GLYCEROL**, carmellose sodium 0.5% + glycerol 0.9% eye drops, 15 mL *(Optive)*

9356K **CARMELLOSE SODIUM + GLYCEROL**, carmellose sodium 0.5% + glycerol 0.9% eye drops, 15 mL *(Optive)*

11193D **EVOLOCUMAB**, evolocumab 420 mg/3.5 mL injection, 3.5 mL cartridge *(Repatha)*

11485L **EVOLOCUMAB**, evolocumab 420 mg/3.5 mL injection, 3.5 mL cartridge *(Repatha)*

11972D **EVOLOCUMAB**, evolocumab 420 mg/3.5 mL injection, 3.5 mL cartridge *(Repatha)*

11986W **EVOLOCUMAB**, evolocumab 420 mg/3.5 mL injection, 3.5 mL cartridge *(Repatha)*

14493T **PARAFFIN**, paraffin 1 g/g eye ointment, 2 x 3.5 g *(Refresh Night Time)*

1750D **PARAFFIN**, paraffin 1 g/g eye ointment, 2 x 3.5 g *(Refresh Night Time)*

5522P **PARAFFIN**, paraffin 1 g/g eye ointment, 2 x 3.5 g *(Refresh Night Time)*

Advance Notices

1 January 2025

Deletion – Brand

13374X *NOUMED ATORVASTATIN, VO* – **ATORVASTATIN**, atorvastatin 80 mg tablet, 30

13468W *NOUMED ATORVASTATIN, VO* – **ATORVASTATIN**, atorvastatin 40 mg tablet, 30

13495G *NOUMED ATORVASTATIN, VO* – **ATORVASTATIN**, atorvastatin 10 mg tablet, 30

13529C *NOUMED ATORVASTATIN, VO* – **ATORVASTATIN**, atorvastatin 20 mg tablet, 30

8213G *NOUMED ATORVASTATIN, VO* – **ATORVASTATIN**, atorvastatin 10 mg tablet, 30

8214H *NOUMED ATORVASTATIN, VO* – **ATORVASTATIN**, atorvastatin 20 mg tablet, 30

8215J *NOUMED ATORVASTATIN, VO* – **ATORVASTATIN**, atorvastatin 40 mg tablet, 30

8521L *NOUMED ATORVASTATIN, VO* – **ATORVASTATIN**, atorvastatin 80 mg tablet, 30

13419G *Cipla Bisoprolol, LR* – **BISOPROLOL**, bisoprolol fumarate 2.5 mg tablet, 28

13443M *Cipla Bisoprolol, LR* – **BISOPROLOL**, bisoprolol fumarate 5 mg tablet, 28

13444N *Cipla Bisoprolol, LR* – **BISOPROLOL**, bisoprolol fumarate 10 mg tablet, 28

8604W *Cipla Bisoprolol, LR* – **BISOPROLOL**, bisoprolol fumarate 2.5 mg tablet, 28

8605X *Cipla Bisoprolol, LR* – **BISOPROLOL**, bisoprolol fumarate 5 mg tablet, 28

8606Y *Cipla Bisoprolol, LR* – **BISOPROLOL**, bisoprolol fumarate 10 mg tablet, 28

8439E *NOUMED CELECOXIB, VO* – **CELECOXIB**, celecoxib 100 mg capsule, 60

8440F *NOUMED CELECOXIB, VO* – **CELECOXIB**, celecoxib 200 mg capsule, 30

2896K *Dimethyl Fumarate MSN, LR* – **DIMETHYL FUMARATE**, dimethyl fumarate 120 mg enteric capsule, 14

2943X *Dimethyl Fumarate MSN, LR* – **DIMETHYL FUMARATE**, dimethyl fumarate 120 mg enteric capsule, 14

2966D *Dimethyl Fumarate MSN, LR* – **DIMETHYL FUMARATE**, dimethyl fumarate 240 mg enteric capsule, 56

9155W *Cymbalta, LY* – **DULOXETINE**, duloxetine 30 mg enteric capsule, 28

9156X *Cymbalta, LY* – **DULOXETINE**, duloxetine 60 mg enteric capsule, 28

14349F *NOUMED ESCITALOPRAM, VO* – **ESCITALOPRAM**, escitalopram 10 mg tablet, 28

14415Q *NOUMED ESCITALOPRAM, VO* – **ESCITALOPRAM**, escitalopram 20 mg tablet, 28

14416R *NOUMED ESCITALOPRAM, VO* – **ESCITALOPRAM**, escitalopram 20 mg tablet, 28

14519E *NOUMED ESCITALOPRAM, VO* – **ESCITALOPRAM**, escitalopram 10 mg tablet, 28

8700X *NOUMED ESCITALOPRAM, VO* – **ESCITALOPRAM**, escitalopram 10 mg tablet, 28

8701Y *NOUMED ESCITALOPRAM, VO* – **ESCITALOPRAM**, escitalopram 20 mg tablet, 28

9432K *NOUMED ESCITALOPRAM, VO* – **ESCITALOPRAM**, escitalopram 10 mg tablet, 28

9433L *NOUMED ESCITALOPRAM, VO* – **ESCITALOPRAM**, escitalopram 20 mg tablet, 28

11692J *Esomeprazole Mylan, AL* – **ESOMEPRAZOLE**, esomeprazole 20 mg enteric tablet, 30

12283L *Esomeprazole Mylan, AL* – **ESOMEPRAZOLE**, esomeprazole 40 mg enteric tablet, 30

12287Q *Esomeprazole Mylan, AL* – **ESOMEPRAZOLE**, esomeprazole 20 mg enteric tablet, 30

14308C *Esomeprazole Mylan, AL* – **ESOMEPRAZOLE**, esomeprazole 20 mg enteric tablet, 30

14373L *Esomeprazole Mylan, AL* – **ESOMEPRAZOLE**, esomeprazole 40 mg enteric tablet, 30

14444F *Esomeprazole Mylan, AL* – **ESOMEPRAZOLE**, esomeprazole 20 mg enteric tablet, 30

14481E *Esomeprazole Mylan, AL* – **ESOMEPRAZOLE**, esomeprazole 20 mg enteric tablet, 30

14512T *Esomeprazole Mylan, AL* – **ESOMEPRAZOLE**, esomeprazole 40 mg enteric tablet, 30

3401B *Esomeprazole Mylan, AL* – **ESOMEPRAZOLE**, esomeprazole 40 mg enteric tablet, 30

8600P *Esomeprazole Mylan, AL* – **ESOMEPRAZOLE**, esomeprazole 20 mg enteric tablet, 30

8601Q *Esomeprazole Mylan, AL* – **ESOMEPRAZOLE**, esomeprazole 40 mg enteric tablet, 30

8886Q *Esomeprazole Mylan, AL* – **ESOMEPRAZOLE**, esomeprazole 20 mg enteric tablet, 30

5262Y *FINGOLIS, LR* – **FINGOLIMOD**, fingolimod 500 microgram capsule, 28

1434L *NOUMED FLUOXETINE, VO* – **FLUOXETINE**, fluoxetine 20 mg capsule, 28

1434L *Prozac 20, LY* – **FLUOXETINE**, fluoxetine 20 mg capsule, 28

14548Q *NOUMED FLUOXETINE, VO* – **FLUOXETINE**, fluoxetine 20 mg capsule, 28

14548Q *Prozac 20, LY* – **FLUOXETINE**, fluoxetine 20 mg capsule, 28

11625W *Genteal, AQ* – **HYPROMELLOSE**, hypromellose 0.3% w/w eye drops, 10 mL

11625W *In a Wink Moisturising, IQ* – **HYPROMELLOSE**, hypromellose 0.3% w/w eye drops, 10 mL

11634H *Genteal, AQ* – **HYPROMELLOSE**, hypromellose 0.3% w/w eye drops, 10 mL

11634H *In a Wink Moisturising, IQ* – **HYPROMELLOSE**, hypromellose 0.3% w/w eye drops, 10 mL

5519L *Genteal gel, AQ* – **HYPROMELLOSE + CARBOMER-980**, hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g

5519L *HPMC PAA, IQ* – **HYPROMELLOSE + CARBOMER-980**, hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g

8564R *Genteal gel, AQ* – **HYPROMELLOSE + CARBOMER-980**, hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g

8564R *HPMC PAA, IQ* – **HYPROMELLOSE + CARBOMER-980**, hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g

9215B *Genteal gel, AQ* – **HYPROMELLOSE + CARBOMER-980**, hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g

9215B *HPMC PAA, IQ* – **HYPROMELLOSE + CARBOMER-980**, hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g

13842M *NOUMED LAMOTRIGINE, VO* – **LAMOTRIGINE**, lamotrigine 25 mg tablet, 56

13843N *NOUMED LAMOTRIGINE, VO* – **LAMOTRIGINE**, lamotrigine 200 mg tablet, 56

13975M *NOUMED LAMOTRIGINE, VO* – **LAMOTRIGINE**, lamotrigine 50 mg tablet, 56

14052N *NOUMED LAMOTRIGINE, VO* – **LAMOTRIGINE**, lamotrigine 100 mg tablet, 56

2848X *NOUMED LAMOTRIGINE, VO* – **LAMOTRIGINE**, lamotrigine 25 mg tablet, 56

2849Y *NOUMED LAMOTRIGINE, VO* – **LAMOTRIGINE**, lamotrigine 50 mg tablet, 56

2850B *NOUMED LAMOTRIGINE, VO* – **LAMOTRIGINE**, lamotrigine 100 mg tablet, 56

2851C *NOUMED LAMOTRIGINE, VO* – **LAMOTRIGINE**, lamotrigine 200 mg tablet, 56

11669E *NOUMED LANSOPRAZOLE, VO* – **LANSOPRAZOLE**, lansoprazole 30 mg enteric capsule, 28

12284M *NOUMED LANSOPRAZOLE, VO* – **LANSOPRAZOLE**, lansoprazole 30 mg enteric capsule, 28

14302R *NOUMED LANSOPRAZOLE, VO* – **LANSOPRAZOLE**, lansoprazole 30 mg enteric capsule, 28

14304W *NOUMED LANSOPRAZOLE, VO* – **LANSOPRAZOLE**, lansoprazole 30 mg enteric capsule, 28

14340R *NOUMED LANSOPRAZOLE, VO* – **LANSOPRAZOLE**, lansoprazole 30 mg enteric capsule, 28

2240X *NOUMED LANSOPRAZOLE, VO* – **LANSOPRAZOLE**, lansoprazole 30 mg enteric capsule, 28

2241Y *NOUMED LANSOPRAZOLE, VO* – **LANSOPRAZOLE**, lansoprazole 30 mg enteric capsule, 28

1324Q *NOUMED METOPROLOL, VO* – **METOPROLOL TARTRATE**, METOPROLOL TARTRATE Tablet 50 mg, 100

1325R *NOUMED METOPROLOL, VO* – **METOPROLOL TARTRATE**, METOPROLOL TARTRATE Tablet 100 mg, 60

13541Q *NOUMED METOPROLOL, VO* – **METOPROLOL TARTRATE**, METOPROLOL TARTRATE Tablet 100 mg, 60

13598Q *NOUMED METOPROLOL, VO* – **METOPROLOL TARTRATE**, METOPROLOL TARTRATE Tablet 50 mg, 100

14037T *Ceptolate, AF* – **MYCOPHENOLATE**, mycophenolate mofetil 250 mg capsule, 50

1836P *Ceptolate, AF* – **MYCOPHENOLATE**, mycophenolate mofetil 250 mg capsule, 50

2522R *NortriTABS 10 mg, GH* – **NORTRIPTYLINE**, nortriptyline 10 mg tablet, 50

2523T *NortriTABS 25 mg, GH* – **NORTRIPTYLINE**, nortriptyline 25 mg tablet, 50

1746X *Parapane, AF* – **PARACETAMOL**, paracetamol 500 mg tablet, 100

5196L *Parapane, AF* – **PARACETAMOL**, paracetamol 500 mg tablet, 100

5224Y *Parapane, AF* – **PARACETAMOL**, paracetamol 500 mg tablet, 100

8784H *Parapane, AF* – **PARACETAMOL**, paracetamol 500 mg tablet, 100

2335X *NOUMED PREGABALIN, VO* – **PREGABALIN**, pregabalin 75 mg capsule, 56

2348N *NOUMED PREGABALIN, VO* – **PREGABALIN**, pregabalin 25 mg capsule, 56

2355Y *Cipla Pregabalin, LR* – **PREGABALIN**, pregabalin 150 mg capsule, 56

2355Y *NOUMED PREGABALIN, VO* – **PREGABALIN**, pregabalin 150 mg capsule, 56

2363J *NOUMED PREGABALIN, VO* – **PREGABALIN**, pregabalin 300 mg capsule, 56

14400X *NOUMED SERTRALINE, VO* – **SERTRALINE**, sertraline 50 mg tablet, 30

14403C *NOUMED SERTRALINE, VO* – **SERTRALINE**, sertraline 50 mg tablet, 30

14404D *NOUMED SERTRALINE, VO* – **SERTRALINE**, sertraline 100 mg tablet, 30

14506L *NOUMED SERTRALINE, VO* – **SERTRALINE**, sertraline 100 mg tablet, 30

2236Q *NOUMED SERTRALINE, VO* – **SERTRALINE**, sertraline 50 mg tablet, 30

2237R *NOUMED SERTRALINE, VO* – **SERTRALINE**, sertraline 100 mg tablet, 30

8836C *NOUMED SERTRALINE, VO* – **SERTRALINE**, sertraline 50 mg tablet, 30

8837D *NOUMED SERTRALINE, VO* – **SERTRALINE**, sertraline 100 mg tablet, 30

13373W *NOUMED SIMVASTATIN, VO* – **SIMVASTATIN**, simvastatin 20 mg tablet, 30

13471B *NOUMED SIMVASTATIN, VO* – **SIMVASTATIN**, simvastatin 40 mg tablet, 30

13528B *NOUMED SIMVASTATIN, VO* – **SIMVASTATIN**, simvastatin 10 mg tablet, 30

2011W *NOUMED SIMVASTATIN, VO* – **SIMVASTATIN**, simvastatin 10 mg tablet, 30

2012X *NOUMED SIMVASTATIN, VO* – **SIMVASTATIN**, simvastatin 20 mg tablet, 30

8173E *NOUMED SIMVASTATIN, VO* – **SIMVASTATIN**, simvastatin 40 mg tablet, 30

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

13593K *NOUMED TELMISARTAN, VO* – **TELMISARTAN**, telmisartan 80 mg tablet, 28

8356T *NOUMED TELMISARTAN, VO* – **TELMISARTAN**, telmisartan 80 mg tablet, 28

1 February 2025

Deletion – Brand

12338J *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12359L *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12361N *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12364R *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12378L *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12379M *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12380N *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12382Q *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12391E *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12397L *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12398M *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12399N *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12400P *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12405X *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12410E *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12413H *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12421R *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12422T *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12430F *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12442W *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12451H *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12453K *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12455M *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13208E *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13209F *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13213K *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13216N *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13217P *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13218Q *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13219R *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13220T *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13222X *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13704G *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13732R *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13763J *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

14586Q *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

14591Y *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

14628X *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

14629Y *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

1 March 2025
Deletion – Brand

14425F *BetoQuin, NM* – **BETAXOLOL**, betaxolol 0.5% eye drops, 5 mL

2825Q *BetoQuin, NM* – **BETAXOLOL**, betaxolol 0.5% eye drops, 5 mL

5544T *BetoQuin, NM* – **BETAXOLOL**, betaxolol 0.5% eye drops, 5 mL

12262J *Protaphane InnoLet, NI* – **INSULIN ISOPHANE HUMAN**, insulin isophane human 100 units/mL injection, 5 x 3 mL pen devices

13380F *Irbesartan GH, GQ* – **IRBESARTAN**, irbesartan 150 mg tablet, 30

13435D *Irbesartan GH, GQ* – **IRBESARTAN**, irbesartan 75 mg tablet, 30

13564X *Irbesartan GH, GQ* – **IRBESARTAN**, irbesartan 300 mg tablet, 30

8246B *Irbesartan GH, GQ* – **IRBESARTAN**, irbesartan 75 mg tablet, 30

8247C *Irbesartan GH, GQ* – **IRBESARTAN**, irbesartan 150 mg tablet, 30

8248D *Irbesartan GH, GQ* – **IRBESARTAN**, irbesartan 300 mg tablet, 30

8816B *Modafinil Mylan, AF* – **MODAFINIL**, modafinil 100 mg tablet, 60

3382B *Olanzapine ODT generichealth 10, GQ* – **OLANZAPINE**, olanzapine 10 mg orally disintegrating tablet, 28

2355Y *Cipla Pregabalin, LR* – **PREGABALIN**, pregabalin 150 mg capsule, 56

2355Y *NOUMED PREGABALIN, VO* – **PREGABALIN**, pregabalin 150 mg capsule, 56

8457D *Quetiapine APOTEX, GX* – **QUETIAPINE**, quetiapine 100 mg tablet, 90

8341B *Imigran, AS* – **SUMATRIPTAN**, sumatriptan 20 mg/actuation nasal spray, 2 x 1 actuation

8526R *Metalyse, BY* – **TENECTEPLASE**, tenecteplase 40 mg injection [1 vial] (&) inert substance diluent [8 mL syringe], 1 pack

Palliative Care

Additions

Addition – Item

14674H **CLONAZEPAM**, clonazepam 2 mg tablet, 100 *(Clonazepam USP (Advagen Pharma, USA))*

Addition – Brand

5368M *WGR-IBUPROFEN 400, WG* – **IBUPROFEN**, ibuprofen 400 mg tablet, 30

12520Y *METHADONE-AFT, AE* – **METHADONE**, methadone hydrochloride 10 mg tablet, 20

Addition – Equivalence Indicator

5338Y *Paxam 2, AF* – **CLONAZEPAM**, clonazepam 2 mg tablet, 100

12520Y *Physeptone, AS* – **METHADONE**, methadone hydrochloride 10 mg tablet, 20

Addition – Note

5338Y **CLONAZEPAM**, clonazepam 2 mg tablet, 100 *(Paxam 2)*

Highly Specialised Drugs Program (Private Hospital)

Additions

Addition – Item

14679N **VEDOLIZUMAB**, vedolizumab 300 mg injection, 1 vial *(Entyvio)*

Addition – Brand

13772W *Zoledronate-DRLA 4, RZ* – **ZOLEDRONIC ACID**, zoledronic acid 4 mg/5 mL injection, 5 mL vial

Deletions

Deletion – Item

11069N **EPOPROSTENOL**, epoprostenol 500 microgram injection [1 vial] (&) inert substance diluent [2 x 50 mL vials], 1 pack *(Flolan)*

11082G **EPOPROSTENOL**, epoprostenol 1.5 mg injection [1 vial] (&) inert substance diluent [2 x 50 mL vials], 1 pack *(Flolan)*

Deletion – Brand

11036W *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

11966T *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 28

12038N *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

12058P *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 14

12071H *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

12984J *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

13642B *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

2798G *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

9642L *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

11063G *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

11969Y *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 28

12004T *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 14

12050F *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

12060R *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

12980E *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

13658W *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

2796E *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

9643M *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

11042E *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

11965R *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 28

12011E *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

12020P *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

12069F *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 14

12986L *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

13657T *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

9644N *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

11055W *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12018M *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 14

12037M *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12068E *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12993W *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

13660Y *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

9645P *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

Deletion – Equivalence Indicator

10111E *Veletri, JC* – **EPOPROSTENOL**, epoprostenol 500 microgram injection, 1 vial

10129D *Veletri, JC* – **EPOPROSTENOL**, epoprostenol 1.5 mg injection, 1 vial

Deletion – Note

10111E **EPOPROSTENOL**, epoprostenol 500 microgram injection, 1 vial *(Veletri)*

10129D **EPOPROSTENOL**, epoprostenol 1.5 mg injection, 1 vial *(Veletri)*

Alterations

Alteration – Manufacturer Code

		From	*To*
12201E	*Cipla Ambrisentan* – **AMBRISENTAN**, ambrisentan 5 mg tablet, 30	LR	ZU
9648T	*Cipla Ambrisentan* – **AMBRISENTAN**, ambrisentan 5 mg tablet, 30	LR	ZU
12180C	*Cipla Ambrisentan* – **AMBRISENTAN**, ambrisentan 10 mg tablet, 30	LR	ZU
9649W	*Cipla Ambrisentan* – **AMBRISENTAN**, ambrisentan 10 mg tablet, 30	LR	ZU

Supply Only

When a product is deleted from the Schedule it may be available under Supply Only rules. Supply Only items/brands are available on the Schedule for dispensing but not for prescribing, usually for a period of up to 12 months from when it is deleted. Substitution of Supply Only items/brands with products flagged as “equivalent for substitution” still apply as specified in the Schedule at the time the script was written.
Further information on Supply Only arrangements is available at https://www.pbs.gov.au/browse/medicine-listing/supply-only

14170T **DAUNORUBICIN + CYTARABINE**, daunorubicin hydrochloride 44 mg + cytarabine 100 mg injection, 1 vial *(Vyxeos)*

14214D **DAUNORUBICIN + CYTARABINE**, daunorubicin hydrochloride 44 mg + cytarabine 100 mg injection, 1 vial *(Vyxeos)*

13826Q **NIVOLUMAB + RELATLIMAB**, nivolumab 240 mg/20 mL + relatlimab 80 mg/20 mL injection, 20 mL vial *(Opdualag)*

13829W **NIVOLUMAB + RELATLIMAB**, nivolumab 240 mg/20 mL + relatlimab 80 mg/20 mL injection, 20 mL vial *(Opdualag)*

Advance Notices

1 January 2025

Deletion – Brand

1837Q *Ceptolate, AF* – **MYCOPHENOLATE**, mycophenolate mofetil 250 mg capsule, 50

1 February 2025

Deletion – Brand

12396K *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13210G *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

Highly Specialised Drugs Program (Public Hospital)

Additions

Addition – Item

14670D **VEDOLIZUMAB**, vedolizumab 300 mg injection, 1 vial *(Entyvio)*

Addition – Brand

13773X *Zoledronate-DRLA 4, RZ* – **ZOLEDRONIC ACID**, zoledronic acid 4 mg/5 mL injection, 5 mL vial

Deletions

Deletion – Item

11090Q **EPOPROSTENOL**, epoprostenol 500 microgram injection [1 vial] (&) inert substance diluent [2 x 50 mL vials], 1 pack *(Flolan)*

11065J **EPOPROSTENOL**, epoprostenol 1.5 mg injection [1 vial] (&) inert substance diluent [2 x 50 mL vials], 1 pack *(Flolan)*

Deletion – Brand

11029L *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

11967W *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 28

12034J *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

12035K *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 14

12039P *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

12985K *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

13636Q *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

2799H *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

5783J *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

11064H *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

11968X *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 28

12057N *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

12061T *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

12070G *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 14

12988N *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

13661B *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

2802L *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

5784K *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

11062F *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

11964Q *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 28

12012F *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 14

12026Y *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

12062W *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

12991R *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

13641Y *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

5785L *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

11041D *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12019N *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 14

12036L *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12059Q *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12979D *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

13630J *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

5786M *Cipla Lenalidomide, LR* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

Deletion – Equivalence Indicator

10130E *Veletri, JC* – **EPOPROSTENOL**, epoprostenol 500 microgram injection, 1 vial

10117L *Veletri, JC* – **EPOPROSTENOL**, epoprostenol 1.5 mg injection, 1 vial

Deletion – Note

10130E **EPOPROSTENOL**, epoprostenol 500 microgram injection, 1 vial *(Veletri)*

10117L **EPOPROSTENOL**, epoprostenol 1.5 mg injection, 1 vial *(Veletri)*

Alterations

Alteration – Manufacturer Code

		From	*To*
12212R	*Cipla Ambrisentan* – **AMBRISENTAN**, ambrisentan 5 mg tablet, 30	LR	ZU
5607D	*Cipla Ambrisentan* – **AMBRISENTAN**, ambrisentan 5 mg tablet, 30	LR	ZU
12186J	*Cipla Ambrisentan* – **AMBRISENTAN**, ambrisentan 10 mg tablet, 30	LR	ZU
5608E	*Cipla Ambrisentan* – **AMBRISENTAN**, ambrisentan 10 mg tablet, 30	LR	ZU

Supply Only

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Further information on Supply Only arrangements is available at https://www.pbs.gov.au/browse/medicine-listing/supply-only

14171W **DAUNORUBICIN + CYTARABINE**, daunorubicin hydrochloride 44 mg + cytarabine 100 mg injection, 1 vial *(Vyxeos)*

14205P **DAUNORUBICIN + CYTARABINE**, daunorubicin hydrochloride 44 mg + cytarabine 100 mg injection, 1 vial *(Vyxeos)*

13817F **NIVOLUMAB + RELATLIMAB**, nivolumab 240 mg/20 mL + relatlimab 80 mg/20 mL injection, 20 mL vial *(Opdualag)*

13830X **NIVOLUMAB + RELATLIMAB**, nivolumab 240 mg/20 mL + relatlimab 80 mg/20 mL injection, 20 mL vial *(Opdualag)*

Advance Notices

1 January 2025

Deletion – Brand

1839T *Ceptolate, AF* – **MYCOPHENOLATE**, mycophenolate mofetil 250 mg capsule, 50

1 February 2025

Deletion – Brand

12431G *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13228F *Adalicip, LR* – **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

Highly Specialised Drugs Program (Community Access)

Deletions

Deletion – Brand

10304H *Nevirapine Alphapharm, AF* – **NEVIRAPINE**, nevirapine 200 mg tablet, 60

Deletion – Equivalence Indicator

10304H *Nevirapine Viatris, AL* – **NEVIRAPINE**, nevirapine 200 mg tablet, 60

Advance Notices

1 January 2025

Deletion – Brand

10357D *Abacavir/Lamivudine Mylan, AF* – **ABACAVIR + LAMIVUDINE**, abacavir 600 mg + lamivudine 300 mg tablet, 30

11155D *Tenofovir Disoproxil Mylan, AF* – **TENOFOVIR DISOPROXIL**, tenofovir disoproxil maleate 300 mg tablet, 30

11982P *Tenofovir Disoproxil Mylan, AF* – **TENOFOVIR DISOPROXIL**, tenofovir disoproxil maleate 300 mg tablet, 30

1 March 2025
Deletion – Brand
10353X *Entecavir Mylan, AF* – **ENTECAVIR**, entecavir 1 mg tablet, 30

Repatriation Pharmaceutical Benefits

Additions

Addition – Brand
4115N *Azithromycin Viatris, AL* – **AZITHROMYCIN**, azithromycin 500 mg tablet, 3

14200J *Tamsulosin Lupin SR, GQ* – **TAMSULOSIN**, tamsulosin hydrochloride 400 microgram modified release tablet, 30

Supply Only

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Further information on Supply Only arrangements is available at https://www.pbs.gov.au/browse/medicine-listing/supply-only

10169F **CLOPIDOGREL**, clopidogrel 75 mg tablet, 28 *(Plidogrel)*

4179Y **CLOPIDOGREL**, clopidogrel 75 mg tablet, 28 *(Clopidogrel Lupin, Clopidogrel Sandoz Pharma, Iscover, Piax, Plavicor 75)*

Advance Notices

1 January 2025
Deletion – Brand
10582Y *Parapane, AF* – **PARACETAMOL**, paracetamol 500 mg tablet, 100

10585D *Parapane, AF* – **PARACETAMOL**, paracetamol 500 mg tablet, 100

General Pharmaceutical Benefits

▪ APOMORPHINE

Note Pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL pen device and pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL cartridge are equivalent for the purposes of substitution.

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

Authority required (STREAMLINED)

15542

Parkinson disease

Treatment Phase: Maintenance therapy

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy, **AND**
- Patient must have been commenced on treatment in a specialist unit in a hospital setting.

apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL cartridges

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14309D NP	40	5	..	*5338.27	31.60	[a] Apomine Intermittent [IT]

apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL pen devices

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14485J NP	40	5	..	*5338.27	31.60	[a] Movapo Pen [TD]

▪ BELZUTIFAN

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

Von Hippel-Lindau (VHL) disease

Treatment Phase: Initiating or recommencing treatment

Clinical criteria:

- The condition must have been diagnosed by at least one of: (i) a germline VHL alteration; (ii) at least two manifestations highly characteristic of VHL disease; (iii) at least one manifestation highly characteristic of VHL disease with a documented family history of VHL, **AND**
- The condition must be at least one of: (i) VHL-associated non-metastatic renal cell carcinoma (RCC); (ii) VHL-associated central nervous system (CNS) haemangioblastoma; (iii) VHL-associated non-metastatic pancreatic neuroendocrine tumour (pNET), **AND**
- Patient must not have tumour(s) that require immediate surgery as assessed by the treating clinician, **AND**
- Patient must be untreated with this drug for this condition; OR
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for a different tumour type; OR
- Patient must have previously received PBS-subsidised treatment with this drug for this condition and ceased previous treatment for family planning purposes, **AND**
- Patient must have WHO performance status no higher than 1; OR
- The condition must be VHL-associated brainstem tumour(s), or brain herniation, which temporarily affected the patient's WHO performance status to be higher than 1, **AND**
- The treatment must be the sole PBS-subsidised therapy for VHL disease associated tumours.

Treatment criteria:

- Must be treated by a physician with expertise in the management of VHL disease associated tumours.

Patients who cease therapy for reasons other than, clinical disease progression or metastasis, may re-initiate PBS-subsidised treatment through the initiating or recommencing treatment phase.

For the purpose of administering this restriction, the highly characteristic manifestations of VHL disease include but not limited to:

(i) retinal, spinal, or cerebellar haemangioblastoma;

(ii) adrenal or extra-adrenal phaeochromocytoma;

(iii) renal cell carcinoma;

(iv) multiple renal and pancreatic cysts;

(v) endolymphatic sac tumours, papillary cystadenomas of the epididymis or broad ligament, or pancreatic neuroendocrine tumours.

Authority required

Von Hippel-Lindau (VHL) disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same tumour type, **AND**
- Patient must not have developed VHL-associated metastatic disease, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of the condition while being treated with this drug, the details of which must be kept with the patient's record, **AND**
- The treatment must be the sole PBS-subsidised therapy for VHL disease associated tumours.

Treatment criteria:

- Must be treated by a physician with expertise in the management of VHL disease associated tumours.

Patients who cease therapy for reasons other than, clinical disease progression or metastasis, may re-initiate PBS-subsidised treatment through the initiating or recommencing treatment phase.

For the purpose of administering this restriction, clinical improvement or stabilisation of the patient's condition includes but is not limited to:

(i) avoidance of surgery;

(ii) avoidance of renal replacement therapy such as dialysis or renal transplantation in patients with VHL- associated renal cell carcinoma (RCC);

(iii) experiencing clinical benefit in at least one of the VHL associated conditions, as determined by the treating clinician(s).

Authority required

Von Hippel-Lindau (VHL) disease

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

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 December 2024, **AND**
- The condition must have been diagnosed by at least one of: (i) a germline VHL alteration; (ii) at least two manifestations highly characteristic of VHL disease; (iii) at least one manifestation highly characteristic of VHL disease with a documented family history of VHL, **AND**
- The condition must have been at least one of the following prior to non-PBS-subsidised treatment with this drug: (i) VHL-associated non-metastatic renal cell carcinoma (RCC); (ii) VHL-associated central nervous system (CNS) haemangioblastoma; (iii) VHL-associated non-metastatic pancreatic neuroendocrine tumour (pNET), **AND**
- Patient must not have had tumour(s) that require immediate surgery as assessed by the treating clinician prior to non-PBS-subsidised treatment with this drug, **AND**
- Patient must have had a WHO performance status score of no greater than 1 at treatment initiation with this drug; OR
- The condition must have been VHL-associated brain stem tumour(s), or brain herniation, which temporarily affected the patient's WHO performance status to be higher than 1 at treatment initiation with this drug, **AND**
- Patient must not have developed VHL-associated metastatic disease, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of the condition, the details of which must be kept with the patient's record. This should be assessed only after a total of 6 months of therapy.

Treatment criteria:

- Must be treated by a physician with expertise in the management of VHL disease associated tumours.

Patients who cease therapy for reasons other than, clinical disease progression or metastasis, may re-initiate PBS-subsidised treatment through the initiating or recommencing treatment phase.

For the purpose of administering this restriction, the highly characteristic manifestations of VHL disease include but not limited to:

(i) retinal, spinal, or cerebellar haemangioblastoma;

(ii) adrenal or extra-adrenal phaeochromocytoma;

(iii) renal cell carcinoma;

(iv) multiple renal and pancreatic cysts;

(v) endolymphatic sac tumours, papillary cystadenomas of the epididymis or broad ligament, or pancreatic neuroendocrine tumours.

For the purpose of administering this restriction, clinical improvement or stabilisation of the patient's condition includes but is not limited to:

(i) avoidance of surgery;

(ii) avoidance of renal replacement therapy such as dialysis or renal transplantation in patients with VHL- associated renal cell carcinoma (RCC);

(iii) experiencing clinical benefit in at least one of the VHL associated conditions, as determined by the treating clinician(s).

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.

belzutifan 40 mg tablet, 90

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14665W	1	5	..	22222.60	31.60	Welireg [MK]

▪ BUDESONIDE

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

6340

Severe chronic asthma

Clinical criteria:

- Patient must require long-term steroid therapy, **AND**
- Patient must not be able to use other forms of inhaled steroid therapy.

budesonide 1 mg/2 mL inhalation solution, 30 x 2 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2066R NP	‡1	5	..	88.72	31.60	Pulmicort Respules [AP]

budesonide 500 microgram/2 mL inhalation solution, 30 x 2 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2065Q NP	‡1	5	..	88.72	31.60	Pulmicort Respules [AP]

▪ BUDESONIDE

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

15578

Severe chronic asthma

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must require long-term steroid therapy, **AND**
- Patient must not be able to use other forms of inhaled steroid therapy.

budesonide 1 mg/2 mL inhalation solution, 30 x 2 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14469M NP	‡2	5	..	*166.51	31.60	Pulmicort Respules [AP]

budesonide 500 microgram/2 mL inhalation solution, 30 x 2 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14438X NP	‡2	5	..	*166.51	31.60	Pulmicort Respules [AP]

▪ CARBAMAZEPINE

Note Pharmaceutical benefits that have the form carbamazepine 200 mg modified release tablet, 200 and pharmaceutical benefits that have the form carbamazepine 200 mg modified release tablet, 100 are equivalent for the purposes of substitution.

carbamazepine 200 mg modified release tablet, 200

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5038E DP	1	..	..	31.24	31.60	[a] Tegretol CR 200 [NV]

carbamazepine 200 mg modified release tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14671E DP	2	..	..	*31.25	31.60	[a] Tegretol CR 200 [NV]

▪ CARBAMAZEPINE

Note Pharmaceutical benefits that have the form carbamazepine 400 mg modified release tablet, 200 and pharmaceutical benefits that have the form carbamazepine 400 mg modified release tablet, 100 are equivalent for the purposes of substitution

carbamazepine 400 mg modified release tablet, 200

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5037D DP	1	..	..	47.24	31.60	[a] Tegretol CR 400 [NV]

carbamazepine 400 mg modified release tablet, 100

14680P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*47.25	31.60	[a] Tegretol CR 400 [NV]

DP

▪ CARBAMAZEPINE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Pharmaceutical benefits that have the form carbamazepine 400 mg modified release tablet, 200 and pharmaceutical benefits that have the form carbamazepine 400 mg modified release tablet, 100 are equivalent for the purposes of substitution

carbamazepine 400 mg modified release tablet, 200

2431Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	47.24	31.60	[a] Tegretol CR 400 [NV]

NP

carbamazepine 400 mg modified release tablet, 100

14666X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*47.25	31.60	[a] Tegretol CR 400 [NV]

NP

▪ CARBAMAZEPINE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Pharmaceutical benefits that have the form carbamazepine 200 mg modified release tablet, 200 and pharmaceutical benefits that have the form carbamazepine 200 mg modified release tablet, 100 are equivalent for the purposes of substitution.

carbamazepine 200 mg modified release tablet, 200

2426Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	31.24	31.60	[a] Tegretol CR 200 [NV]

NP

carbamazepine 200 mg modified release tablet, 100

14681Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*31.25	31.60	[a] Tegretol CR 200 [NV]

NP

▪ CARBAMAZEPINE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Pharmaceutical benefits that have the form carbamazepine 400 mg modified release tablet, 200 and pharmaceutical benefits that have the form carbamazepine 400 mg modified release tablet, 100 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.

carbamazepine 400 mg modified release tablet, 200

13918M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*81.03	31.60	[a] Tegretol CR 400 [NV]

NP

carbamazepine 400 mg modified release tablet, 100

14662Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	2	..	*81.03	31.60	[a] Tegretol CR 400 [NV]

NP

▪ CARBAMAZEPINE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Pharmaceutical benefits that have the form carbamazepine 200 mg modified release tablet, 200 and pharmaceutical benefits that have the form carbamazepine 200 mg modified release tablet, 100 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.

carbamazepine 200 mg modified release tablet, 200

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14050L NP	2	2	..	*49.03	31.60	[a] Tegretol CR 200 [NV]

carbamazepine 200 mg modified release tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14673G NP	4	2	..	*49.03	31.60	[a] Tegretol CR 200 [NV]

▪ CLONAZEPAM

Caution Abuse of clonazepam has been reported. Refer to the current product information.

Note Pharmaceutical benefits that have the brand Clonazepam USP (Advagen Pharma, USA) may be substituted for pharmaceutical benefits that have the brand Paxam 2 in the case of shortage.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required

Epilepsy

Clinical criteria:

- The condition must be neurologically proven.

clonazepam 2 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14675J NP	2	2	..	*99.17	31.60	[a] Clonazepam USP (Advagen Pharma, USA) [LM]

clonazepam 2 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1806C NP	2	2	..	*32.45	31.60	[a] Paxam 2 [AF]

▪ DAPAGLIFLOZIN

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Abbreviations used in the restriction are as follows:
SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

Authority required (STREAMLINED)

16220

Diabetes mellitus type 2

Clinical criteria:

- The treatment must be in combination with metformin; unless contraindicated/intolerant, **AND**
- Patient must have cardiovascular disease; OR
- Patient must be at high risk of a cardiovascular event; OR
- Patient must identify as Aboriginal or Torres Strait Islander.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment for this condition with any of: (i) a GLP-1 receptor agonist, (ii) another SGLT2 inhibitor.

Note The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au.
High cardiovascular risk is defined as an estimated risk of a cardiovascular event of at least 10% over 5 years.

Authority required (STREAMLINED)

15311

Diabetes mellitus type 2

Clinical criteria:

- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor.

Note Definition:
A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.
Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:
(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
(b) Red cell transfusion within the previous 3 months.

Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

dapagliflozin 10 mg tablet, 28

10011X NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	52.82	31.60	Forxiga [AP]

▪ DAPAGLIFLOZIN

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Abbreviations used in the restriction are as follows:
SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

Authority required (STREAMLINED)

16164

Diabetes mellitus type 2

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be in combination with metformin; unless contraindicated/intolerant, **AND**
- Patient must have cardiovascular disease; OR
- Patient must be at high risk of a cardiovascular event; OR
- Patient must identify as Aboriginal or Torres Strait Islander.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment for this condition with any of: (i) a GLP-1 receptor agonist, (ii) another SGLT2 inhibitor.

Note The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au.
High cardiovascular risk is defined as an estimated risk of a cardiovascular event of at least 10% over 5 years.

Authority required (STREAMLINED)

15265

Diabetes mellitus type 2

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor.

Note Definition:
A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.
Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:
(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
(b) Red cell transfusion within the previous 3 months.
Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

dapagliflozin 10 mg tablet, 28

13844P NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*92.19	31.60	Forxiga [AP]

▪ DAPAGLIFLOZIN + METFORMIN

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Abbreviations used in the restriction are as follows:
SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

Authority required (STREAMLINED)

16158

Diabetes mellitus type 2

Clinical criteria:

- Patient must have cardiovascular disease; OR
- Patient must be at high risk of a cardiovascular event; OR
- Patient must identify as Aboriginal or Torres Strait Islander.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment for this condition with any of: (i) a GLP-1 receptor agonist, (ii) another SGLT2 inhibitor.

Note The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au.
High cardiovascular risk is defined as an estimated risk of a cardiovascular event of at least 10% over 5 years.

Authority required (STREAMLINED)

15289

Diabetes mellitus type 2

Clinical criteria:

- The condition must be inadequately responsive to metformin.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor.

Note Definition:
A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.
Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:
(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
(b) Red cell transfusion within the previous 3 months.
Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

dapagliflozin 5 mg + metformin hydrochloride 1 g modified release tablet, 56

10510E NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	54.65	31.60	Xigduo XR 5/1000 [AP]

dapagliflozin 10 mg + metformin hydrochloride 1 g modified release tablet, 28

10515K NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	53.35	31.60	Xigduo XR 10/1000 [AP]

dapagliflozin 10 mg + metformin hydrochloride 500 mg modified release tablet, 28

10516L NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	52.57	31.60	Xigduo XR 10/500 [AP]

▪ DAPAGLIFLOZIN + METFORMIN

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Abbreviations used in the restriction are as follows:
SGLT2 - sodium glucose co-transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

Authority required (STREAMLINED)

16162

Diabetes mellitus type 2

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have cardiovascular disease; OR
- Patient must be at high risk of a cardiovascular event; OR
- Patient must identify as Aboriginal or Torres Strait Islander.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment for this condition with any of: (i) a GLP-1 receptor agonist, (ii) another SGLT2 inhibitor.

Note The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au.
High cardiovascular risk is defined as an estimated risk of a cardiovascular event of at least 10% over 5 years.

Authority required (STREAMLINED)

15267

Diabetes mellitus type 2

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**

- The condition must be inadequately responsive to metformin.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor.

Note Definition:
A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.
Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:
(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
(b) Red cell transfusion within the previous 3 months.
Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

dapagliflozin 5 mg + metformin hydrochloride 1 g modified release tablet, 56

13851B NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*95.85	31.60	Xigduo XR 5/1000 [AP]

dapagliflozin 10 mg + metformin hydrochloride 1 g modified release tablet, 28

13875G NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*93.25	31.60	Xigduo XR 10/1000 [AP]

dapagliflozin 10 mg + metformin hydrochloride 500 mg modified release tablet, 28

14028H NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*91.69	31.60	Xigduo XR 10/500 [AP]

▪ DIENOGEST

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

16222
Endometriosis

dienogest 2 mg tablet, 28

14667Y NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	57.70	31.60	Visanne [BN]

▪ EZETIMIBE

Note Pharmaceutical benefits that have the form ezetimibe tablet 10 mg can be substituted for Ezetimibe USP (Camber, USA) in the case of a shortage.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

ezetimibe 10 mg tablet, 30

8757X NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	19.10	20.55	[a] APO-Ezetimibe [TX]	[a] BTC Ezetimibe [BG]
					[a] EZEMICHOL [RW]	[a] Ezetimibe GH [GQ]
					[a] Ezetimibe Sandoz [SZ]	[a] EZETIMIBE-WGR [WG]
					[a] Pharmacor Ezetimibe 10 [CR]	[a] Zient 10mg [AF]
		[B]2.16	21.26	20.55	[a] Ezetrol [AL]	

ezetimibe 10 mg tablet, 90

14682R NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
0.33	5	..	*29.69	31.14	[a] Ezetimibe USP (Camber, USA) [RQ]

▪ EZETIMIBE

Note Pharmaceutical benefits that have the form ezetimibe tablet 10 mg can be substituted for Ezetimibe USP (Camber, USA) in the case of a shortage.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

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

ezetimibe 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13440J NP	2	5	..	*24.75	26.20	[a] APO-Ezetimibe [TX] [a] EZEMICHOL [RW] [a] Ezetimibe Sandoz [SZ] [a] Pharmacor Ezetimibe 10 [CR]	[a] BTC Ezetimibe [BG] [a] Ezetimibe GH [GQ] [a] EZETIMIBE-WGR [WG] [a] Zient 10mg [AF]
			[B]4.32	*29.07	26.20	[a] Ezetrol [AL]	

ezetimibe 10 mg tablet, 90

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14668B NP	0.67	5	..	*35.63	31.60	[a] Ezetimibe USP (Camber, USA) [RQ]

▪ LISDEXAMFETAMINE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note In accordance with the Therapeutic Goods Administration (TGA)-approved Product Information, this PBS listing currently intends for once daily dosing only with PBS treatment. Divided dosing of PBS treatment is not intended (e.g. 20 mg in the mornings, 30 mg in the evenings). Where applications (either on the same day or on separate days) for multiple strengths are sought with an intent to titrate patient's dosage, repeats should only be sought for the listed target strength

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

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

Attention deficit hyperactivity disorder

Clinical criteria:

- Patient must require continuous coverage over 12 hours, **AND**
- The treatment must not exceed a maximum daily dose of 70 mg of PBS-subsidised treatment with this drug.

Population criteria:

- Patient must be or have been diagnosed between the ages of 6 and 17 years inclusive; OR
- Patient must have had a diagnosis of ADHD prior to turning 18 years of age if PBS-subsidised treatment is continuing beyond 18 years of age; OR
- Patient must have a retrospective diagnosis of ADHD if PBS-subsidised treatment is commencing after turning 18 years of age; OR
- Patient must have had a retrospective diagnosis of ADHD if PBS-subsidised treatment is continuing in a patient who commenced PBS-subsidised treatment after turning 18 years of age.

A retrospective diagnosis of ADHD for the purposes of administering this restriction is:

(i) the presence of pre-existing childhood symptoms of ADHD (onset during the developmental period, typically early to mid-childhood); and

(ii) documentation in the patient's medical records that an in-depth clinical interview with, or, obtainment of evidence from, either a: (a) parent, (b) teacher, (c) sibling, (d) third party**,** has occurred and which supports point (i) above.

lisdexamfetamine dimesilate 20 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11884L NP	1	5	..	100.65	31.60	Vyvanse [TK]

lisdexamfetamine dimesilate 40 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11898F NP	1	5	..	100.65	31.60	Vyvanse [TK]

lisdexamfetamine dimesilate 60 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11897E NP	1	5	..	100.65	31.60	Vyvanse [TK]

lisdexamfetamine dimesilate 30 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10486X NP	1	5	..	100.65	31.60	Vyvanse [TK]

lisdexamfetamine dimesilate 70 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10492F NP	1	5	..	100.65	31.60	Vyvanse [TK]

lisdexamfetamine dimesilate 50 mg capsule, 30

10474G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	100.65	31.60	Vyvanse [TK]

NP

▪ METHYLPHENIDATE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note In accordance with the Therapeutic Goods Administration (TGA)-approved Product Information, this PBS listing currently intends for once daily dosing only with PBS treatment. Divided dosing of PBS treatment is not intended (e.g. 20 mg in the mornings, 30 mg in the evenings). Where applications (either on the same day or on separate days) for multiple strengths are sought with an intent to titrate patient's dosage, repeats should only be sought for the listed target strength

Note A patient may only receive PBS-subsidised treatment with one form of long-acting methylphenidate at any one time.

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

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

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

Authority required

Attention deficit hyperactivity disorder

Clinical criteria:

- Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events, **AND**
- Patient must require continuous coverage over 8 hours, **AND**
- The treatment must not exceed a maximum daily dose of 80 mg of PBS-subsidised treatment with this drug.

Population criteria:

- Patient must be or have been diagnosed between the ages of 6 and 17 years inclusive; OR
- Patient must have had a diagnosis of ADHD prior to turning 18 years of age if PBS-subsidised treatment is continuing beyond 18 years of age; OR
- Patient must have a retrospective diagnosis of ADHD if PBS-subsidised treatment is commencing after turning 18 years of age; OR
- Patient must have had a retrospective diagnosis of ADHD if PBS-subsidised treatment is continuing in a patient who commenced PBS-subsidised treatment after turning 18 years of age.

A retrospective diagnosis of ADHD for the purposes of administering this restriction is:

(i) the presence of pre-existing childhood symptoms of ADHD (onset during the developmental period, typically early to mid-childhood); and

(ii) documentation in the patient's medical records that an in-depth clinical interview with, or, obtainment of evidence from, either a: (a) parent, (b) teacher, (c) sibling, (d) third party**,** has occurred and which supports point (i) above.

methylphenidate hydrochloride 40 mg modified release capsule, 30

2283E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	55.13	31.60	[a] Ritalin LA [NV]	[a] Rubifen LA [AE]

NP

▪ METHYLPHENIDATE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note In accordance with the Therapeutic Goods Administration (TGA)-approved Product Information, this PBS listing currently intends for once daily dosing only with PBS treatment. Divided dosing of PBS treatment is not intended (e.g. 18 mg in the mornings, 36 mg in the evenings). Where applications (either on the same day or on separate days) for multiple strengths are sought with an intent to titrate patient's dosage, repeats should only be sought for the listed target strength

Note A patient may only receive PBS-subsidised treatment with one form of long-acting methylphenidate at any one time.

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

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

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

Authority required

Attention deficit hyperactivity disorder

Clinical criteria:

- Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events, **AND**
- Patient must require continuous coverage over 12 hours, **AND**
- The treatment must not exceed a maximum daily dose of 72 mg of PBS-subsidised treatment with this drug.

Population criteria:

- Patient must be or have been diagnosed between the ages of 6 and 17 years inclusive.

methylphenidate hydrochloride 36 mg modified release tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2388Q NP	1	5	..	59.59	31.60	[a] Concerta [JC] [a] Methylphenidate XR ARX [XT]	[a] METHYLPHENIDATE-TEVA XR [TB]

▪ METHYLPHENIDATE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note In accordance with the Therapeutic Goods Administration (TGA)-approved Product Information, this PBS listing currently intends for once daily dosing only with PBS treatment. Divided dosing of PBS treatment is not intended (e.g. 20 mg in the mornings, 30 mg in the evenings). Where applications (either on the same day or on separate days) for multiple strengths are sought with an intent to titrate patient's dosage, repeats should only be sought for the listed target strength

Note A patient may only receive PBS-subsidised treatment with one form of long-acting methylphenidate at any one time.

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

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.

Authority required

Attention deficit hyperactivity disorder

Clinical criteria:

- Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events, **AND**
- Patient must require continuous coverage over 8 hours, **AND**
- The treatment must not exceed a maximum daily dose of 80 mg of PBS-subsidised treatment with this drug.

Population criteria:

- Patient must be or have been diagnosed between the ages of 6 and 17 years inclusive; OR
- Patient must have had a diagnosis of ADHD prior to turning 18 years of age if PBS-subsidised treatment is continuing beyond 18 years of age; OR
- Patient must have a retrospective diagnosis of ADHD if PBS-subsidised treatment is commencing after turning 18 years of age; OR
- Patient must have had a retrospective diagnosis of ADHD if PBS-subsidised treatment is continuing in a patient who commenced PBS-subsidised treatment after turning 18 years of age.

A retrospective diagnosis of ADHD for the purposes of administering this restriction is:

(i) the presence of pre-existing childhood symptoms of ADHD (onset during the developmental period, typically early to mid-childhood); and

(ii) documentation in the patient's medical records that an in-depth clinical interview with, or, obtainment of evidence from, either a: (a) parent, (b) teacher, (c) sibling, (d) third party**,** has occurred and which supports point (i) above.

methylphenidate hydrochloride 60 mg modified release capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
12116Q NP	1	5	..	67.46	31.60	[a] Ritalin LA [NV]	[a] Rubifen LA [AE]

methylphenidate hydrochloride 10 mg modified release capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3440C NP	1	5	..	38.04	31.60	[a] Ritalin LA [NV]	[a] Rubifen LA [AE]

methylphenidate hydrochloride 20 mg modified release capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2276T NP	1	5	..	46.27	31.60	[a] Ritalin LA [NV]	[a] Rubifen LA [AE]

methylphenidate hydrochloride 30 mg modified release capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2280B NP	1	5	..	52.87	31.60	[a] Ritalin LA [NV]	[a] Rubifen LA [AE]

▪ METHYLPHENIDATE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note In accordance with the Therapeutic Goods Administration (TGA)-approved Product Information, this PBS listing currently intends for once daily dosing only with PBS treatment. Divided dosing of PBS treatment is not intended (e.g. 18 mg in the mornings, 36 mg in the evenings). Where applications (either on the same day or on separate days) for multiple strengths are sought with an intent to titrate patient's dosage, repeats should only be sought for the listed target strength

Note A patient may only receive PBS-subsidised treatment with one form of long-acting methylphenidate at any one time.

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

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.

Authority required

Attention deficit hyperactivity disorder

Clinical criteria:

- Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events, **AND**
- Patient must require continuous coverage over 12 hours, **AND**
- The treatment must not exceed a maximum daily dose of 72 mg of PBS-subsidised treatment with this drug.

Population criteria:

- Patient must be or have been diagnosed between the ages of 6 and 17 years inclusive.

methylphenidate hydrochloride 18 mg modified release tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2387P NP	1	5	..	52.25	31.60	[a] Concerta [JC]	[a] METHYLPHENIDATE-TEVA XR [TB]
						[a] Methylphenidate XR ARX [XT]	

methylphenidate hydrochloride 27 mg modified release tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2172H NP	1	5	..	55.91	31.60	[a] Concerta [JC]	[a] METHYLPHENIDATE-TEVA XR [TB]
						[a] Methylphenidate XR ARX [XT]	

methylphenidate hydrochloride 54 mg modified release tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2432B NP	1	5	..	67.70	31.60	[a] Concerta [JC]	[a] METHYLPHENIDATE-TEVA XR [TB]
						[a] Methylphenidate XR ARX [XT]	

▪ MOLNUPIRAVIR

Note Details of the Liverpool COVID-19 Drug interaction checker can be found at: https://www.covid19-druginteractions.org/checker

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)

16190

SARS-CoV-2 infection

Clinical criteria:

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

Population criteria:

- Patient must be at least 70 years of age.

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

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

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

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

For the purpose of administering this restriction, the contraindications to nirmatrelvir (&) ritonavir can be found using the Liverpool COVID-19 Drug interaction checker or the TGA-approved Product Information for Paxlovid.

Details/reasons of contraindications to nirmatrelvir (&) ritonavir must be documented in the patient's medical records.

Authority required (STREAMLINED)

16191

SARS-CoV-2 infection

Clinical criteria:

- The treatment must be for use when nirmatrelvir (&) ritonavir is contraindicated, **AND**
- Patient must have received a positive nucleic acid test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**

- Patient must satisfy at least one of the following criteria: (i) be moderately to severely immunocompromised with risk of progression to severe COVID-19 disease due to the immunocompromised status, (ii) has experienced past COVID-19 infection resulting in hospitalisation, **AND**
- The treatment must be initiated within 5 days of symptom onset.

Population criteria:

- Patient must be at least 18 years of age.

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

1. Any primary or acquired immunodeficiency including:

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

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

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

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

a. Chemotherapy or whole body radiotherapy,

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

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

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

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

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

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

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

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

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

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

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

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

For the purpose of administering this restriction, the contraindications to nirmatrelvir (&) ritonavir can be found using the Liverpool COVID-19 Drug interaction checker or the TGA-approved Product Information for Paxlovid.

Details/reasons of contraindications to nirmatrelvir (&) ritonavir must be documented in the patient's medical records.

Authority required (STREAMLINED)

16200

SARS-CoV-2 infection

Clinical criteria:

- The treatment must be for use when nirmatrelvir (&) ritonavir is contraindicated, **AND**
- Patient must have received a positive nucleic acid test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset.

Population criteria:

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

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

1. The patient is in residential aged care

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

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

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

5. Heart failure, coronary artery disease, cardiomyopathies

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

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

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

9. Cirrhosis

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

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

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

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

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

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

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

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

For the purpose of administering this restriction, the contraindications to nirmatrelvir (&) ritonavir can be found using the Liverpool COVID-19 Drug interaction checker or the TGA-approved Product Information for Paxlovid.

Details/reasons of contraindications to nirmatrelvir (&) ritonavir must be documented in the patient's medical records.

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

Authority required (STREAMLINED)

16201

SARS-CoV-2 infection

Clinical criteria:

- The treatment must be for use when nirmatrelvir (&) ritonavir is contraindicated, **AND**
- Patient must have received a positive nucleic acid test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- The treatment must be initiated within 5 days of symptom onset.

Population criteria:

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

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

1. The patient is in residential aged care,

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

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

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

5. Heart failure, coronary artery disease, cardiomyopathies,

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

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

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

9. Cirrhosis, or

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

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

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

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

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

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

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

For the purpose of administering this restriction, the contraindications to nirmatrelvir (&) ritonavir can be found using the Liverpool COVID-19 Drug interaction checker or the TGA-approved Product Information for Paxlovid.

Details/reasons of contraindications to nirmatrelvir (&) ritonavir must be documented in the patient's medical records.

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

molnupiravir 200 mg capsule, 40

12910L

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	1102.71	31.60	Lagevrio [MK]

▪ NIRMATRELVIR (&) RITONAVIR

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

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

16155

SARS-CoV-2 infection

Clinical criteria:

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

Population criteria:

- Patient must be at least 70 years of age.

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

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

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

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

Authority required (STREAMLINED)

16223

SARS-CoV-2 infection

Clinical criteria:

- Patient must have received a positive nucleic acid test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- Patient must satisfy at least one of the following criteria: (i) be moderately to severely immunocompromised with risk of progression to severe COVID-19 disease due to the immunocompromised status, (ii) has experienced past COVID-19 infection resulting in hospitalisation, **AND**
- The treatment must be initiated within 5 days of symptom onset.

Population criteria:

- Patient must be at least 18 years of age.

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

1. Any primary or acquired immunodeficiency including:

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

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

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

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

a. Chemotherapy or whole body radiotherapy,

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

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

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

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

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

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

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

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

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

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

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

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

Authority required (STREAMLINED)

16192

SARS-CoV-2 infection

Clinical criteria:

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

Population criteria:

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

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

1. The patient is in residential aged care
2. The patient has disability with multiple comorbidities and/or frailty
3. Neurological conditions, including stroke and dementia and demyelinating conditions
4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease
5. Heart failure, coronary artery disease, cardiomyopathies
6. Obesity (BMI greater than 30 kg/m^2)
7. Diabetes type I or II, requiring medication for glycaemic control
8. Renal impairment (eGFR less than 60mL/min)
9. Cirrhosis
10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above
11. Past COVID-19 infection episode resulting in hospitalisation.

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

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

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

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

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

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

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

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Authority required (STREAMLINED)

16156

SARS-CoV-2 infection

Clinical criteria:

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

Population criteria:

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

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

1. The patient is in residential aged care,
2. The patient has disability with multiple comorbidities and/or frailty,
3. Neurological conditions, including stroke and dementia and demyelinating conditions,
4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease,
5. Heart failure, coronary artery disease, cardiomyopathies,
6. Obesity (BMI greater than 30 kg/m^2),
7. Diabetes type I or II, requiring medication for glycaemic control,
8. Renal impairment (eGFR less than 60mL/min),
9. Cirrhosis, or
10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above.

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

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

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

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

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

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

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

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

12996B NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	1115.31	31.60	Paxlovid [PF]

▪ TESTOSTERONE

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

Androgen deficiency

Clinical criteria:

- Patient must have an established pituitary or testicular disorder.

Treatment criteria:

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The treatment must be applied to the scrotum, where possible.

The name of the specialist must be included in the authority application.

Authority required

Androgen deficiency

Clinical criteria:

- Patient must not have an established pituitary or testicular disorder, **AND**
- The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

Population criteria:

- Patient must be aged 40 years or older.

Treatment criteria:

- Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The treatment must be applied to the scrotum, where possible.

Androgen deficiency is defined as:

(i) testosterone level of less than 6 nmol per litre; OR

(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonodal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

The name of the specialist must be included in the authority application.

Authority required

Micropenis

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The treatment must be applied to the scrotum, where possible.

The name of the specialist must be included in the authority application.

Authority required

Pubertal induction

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The treatment must be applied to the scrotum, where possible.

The name of the specialist must be included in the authority application.

Authority required

Constitutional delay of growth or puberty

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The treatment must be applied to the scrotum, where possible.

The name of the specialist must be included in the authority application.

testosterone 5% (50 mg/mL) cream, 50 mL

10378F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	107.54	31.60	AndroForte 5 [LX]

▪ TESTOSTERONE

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

Androgen deficiency

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have an established pituitary or testicular disorder.

Treatment criteria:

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The treatment must be applied to the scrotum, where possible.

The name of the specialist must be included in the authority application.

Authority required

Androgen deficiency

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must not have an established pituitary or testicular disorder, **AND**
- The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

Population criteria:

- Patient must be aged 40 years or older.

Treatment criteria:

- Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The treatment must be applied to the scrotum, where possible.

Androgen deficiency is defined as:

(i) testosterone level of less than 6 nmol per litre; OR

(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonodal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

The name of the specialist must be included in the authority application.

Authority required

Micropenis

Clinical criteria:

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

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The treatment must be applied to the scrotum, where possible.

The name of the specialist must be included in the authority application.

Authority required

Pubertal induction

Clinical criteria:

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

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The treatment must be applied to the scrotum, where possible.

The name of the specialist must be included in the authority application.

Authority required

Constitutional delay of growth or puberty

Clinical criteria:

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

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a specialist general paediatrician**,** specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The treatment must be applied to the scrotum, where possible.

The name of the specialist must be included in the authority application.

testosterone 5% (50 mg/mL) cream, 50 mL

14563L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡2	1	..	*206.03	31.60	AndroForte 5 [LX]

Palliative Care

▪ CLONAZEPAM

Note Pharmaceutical benefits that have the brand Clonazepam USP (Advagen Pharma, USA) may be substituted for pharmaceutical benefits that have the brand Paxam 2 in the case of shortage.

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

Restricted benefit

For use in patients receiving palliative care

clonazepam 2 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14674H NP	1	3	..	56.31	31.60	[a] Clonazepam USP (Advagen Pharma, USA) [LM]

clonazepam 2 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5338Y NP	1	3	..	22.95	24.40	[a] Paxam 2 [AF]

Highly Specialised Drugs Program (Private Hospital)

▪ VEDOLIZUMAB

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

Moderate to severe chronic pouchitis

Treatment Phase: Initial 1 treatment (new patient)

Clinical criteria:

- Patient must have undergone ileal pouch anal anastomosis (IPAA) due to ulcerative colitis (UC) at least one year previously, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be confirmed based on the patient's symptoms, treatment history and baseline endoscopic examination of the pouch (pouchoscopy), **AND**
- Patient must have a Modified Pouchitis Disease Activity Index (mPDAI) score of at least 5, **AND**
- Patient must have a minimum endoscopic mPDAI sub-score of at least 2, **AND**
- Patient must have had at least 3 recurrent episodes of pouchitis within the previous year each of which was treated with at least: (i) 2 weeks of antibiotic, (ii) other prescription therapy; OR
- The condition must have required maintenance antibiotic therapy taken continuously for at least 4 weeks before commencing treatment with this drug, **AND**
- Patient must not receive more than 14 weeks of treatment under this restriction.

Treatment criteria:

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

Clinical criteria:

- The treatment must be initiated in combination with standard of care antibiotic.

The assessment of a patient's response to this initial course of treatment must be made after the third dose of vedolizumab so there is an adequate time for a response to be demonstrated. The assessment must be made prior to obtaining a PBS authority for continuing treatment from the dose at week 14. Where a response assessment is not conducted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

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

(a) details of the proposed prescription; 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) which includes the following:

(i) the patient's baseline Modified Pouchitis Disease Activity Index (mPDAI) score and endoscopic mPDAI subscore; and

(ii) details of prior drug therapy for this condition [dosage, date of commencement and duration of therapy].

The endoscopic assessment contributing to the Modified Pouchitis Disease Activity Index score to confirm the patient's condition at baseline must have been performed no more than 4 weeks prior to the application.

Applications for treatment of this condition must be received within 4 weeks of the endoscopy to confirm diagnosis.

The prescriber must exclude secondary causes of pouchitis, for example:

(a) Ischaemia;

(b) Crohn's disease (CD) or CD of the pouch;

(c) Irritable pouch syndrome;

(d) Predominant cuffitis;

(e) Pouch stricture or pouch fistula;

(f) Active infection;

(g) NSAIDs;

(h) Coeliac disease.

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

Moderate to severe chronic pouchitis

Treatment Phase: Initial 2 treatment (Recommencement of treatment after a break in biological medicine)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 14 weeks of treatment under this restriction.

Treatment criteria:

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

Clinical criteria:

- The treatment must be initiated in combination with standard of care antibiotic.

The assessment of a patient's response to this initial course of treatment must be made after the third dose of vedolizumab so there is adequate time for a response to be demonstrated. The assessment must be made prior to obtaining a PBS authority for continuing treatment from the dose at week 14.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond 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.

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

(a) details of the proposed prescription; 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) which includes the following:

(i) the patient's baseline Modified Pouchitis Disease Activity Index (mPDAI) score and minimum endoscopic mPDAI sub-score; and

(ii) details of prior biological medicine therapy for this condition, [date of commencement and duration of therapy].

The endoscopic assessment contributing to the Modified Pouchitis Disease Activity Index score to confirm the patient's condition at baseline must have been performed no more than 4 weeks prior to the application.

Applications for treatment of this condition must be received within 4 weeks of the endoscopy to confirm diagnosis.

The prescriber must exclude secondary causes of pouchitis, for example:

(a) Ischaemia;

(b) Crohn's disease (CD) or CD of the pouch;

(c) Irritable pouch syndrome;

(d) Predominant cuffitis;

(e) Pouch stricture or pouch fistula;

(f) Active infection;

(g) NSAIDs;

(h) Coeliac disease.

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

Moderate to severe chronic pouchitis

Treatment Phase: Balance of Supply - Initial 1 treatment (new patient) and Initial 2 treatment (recommencement of treatment after a break in biological medicine)

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 treatment (new patient) restriction to complete 14 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 treatment (recommencement of treatment after a break in biological medicine) to complete 14 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 14 weeks treatment available under the above treatment phases.

Treatment criteria:

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

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

Moderate to severe chronic pouchitis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received this drug as their most recent course of PBS-subsidised biological medicine for this condition, **AND**
- Patient must have demonstrated or sustained a partial or complete response, as determined by the treating clinician, to the most recent PBS-subsidised course of treatment with this drug for this condition.

Treatment criteria:

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

Patients who have failed to demonstrate a partial or complete response with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

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

An application for the continuing treatment must be made following the third dose with this drug and requested no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where an application is not made within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

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

Moderate to severe chronic pouchitis

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

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 December 2024, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- Patient must have undergone ileal pouch anal anastomosis (IPAA) due to ulcerative colitis at least one year prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be confirmed based on the patient's symptoms, treatment history and baseline endoscopic examination of the pouch (pouchoscopy), **AND**
- Patient must have had a Modified Pouchitis Disease Activity Index (mPDAI) score of at least 5 at the time of initiating treatment with this drug for this condition, **AND**
- Patient must have had a minimum endoscopic mPDAI sub-score of at least 2 at the time of initiating treatment with this drug for this condition, **AND**
- Patient must had at least 3 recurrent episodes of pouchitis within the year prior to initiating treatment with this drug for this condition, each of which was treated with at least 2 weeks of antibiotic or other prescription therapy; OR
- The condition must have required maintenance antibiotic therapy taken continuously for at least 4 weeks before commencing treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must have been initiated in combination with standard of care antibiotic, **AND**
- Patient must have demonstrated a partial or complete response to treatment with this drug as determined by the treating clinician, for this condition if the patient has received non-PBS-subsidised treatment for the first three doses of induction.

Treatment criteria:

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

The assessment of a patient's response to this course of treatment must be made after the third dose of vedolizumab so there is adequate time for a response to be demonstrated. The assessment must be made prior to obtaining a PBS authority for continuing treatment from the dose at week 14.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

The application for authorisation of treatment must be in writing and must include:

(a) details of the proposed prescription; 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) which includes the following:

(i) the patient's baseline Modified Pouchitis Disease Activity Index (mPDAI) score and minimum endoscopic mPDAI sub-score; and

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

(iii) the date of commencement of this drug for this condition.

The endoscopic assessment contributing to the Modified Pouchitis Disease Activity Index score to confirm the patient's condition at baseline must have been performed no more than 4 weeks prior to initiation with non-PBS-subsidised treatment with this drug.

The prescriber must have excluded secondary causes of pouchitis, for example:

(a) Ischaemia;

(b) Crohn's disease (CD) or CD of the pouch;

(c) Irritable pouch syndrome;

(d) Predominant cuffitis;

(e) Pouch stricture or pouch fistula;

(f) Active infection;

(g) NSAIDs;

(h) Coeliac disease.

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

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

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

vedolizumab 300 mg injection, 1 vial

14679N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	..	2998.60	Entyvio [TK]

Highly Specialised Drugs Program (Public Hospital)

▪ VEDOLIZUMAB

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

Moderate to severe chronic pouchitis

Treatment Phase: Initial 1 treatment (new patient)

Clinical criteria:

- Patient must have undergone ileal pouch anal anastomosis (IPAA) due to ulcerative colitis (UC) at least one year previously, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be confirmed based on the patient's symptoms, treatment history and baseline endoscopic examination of the pouch (pouchoscopy), **AND**
- Patient must have a Modified Pouchitis Disease Activity Index (mPDAI) score of at least 5, **AND**
- Patient must have a minimum endoscopic mPDAI sub-score of at least 2, **AND**
- Patient must have had at least 3 recurrent episodes of pouchitis within the previous year each of which was treated with at least: (i) 2 weeks of antibiotic, (ii) other prescription therapy; OR
- The condition must have required maintenance antibiotic therapy taken continuously for at least 4 weeks before commencing treatment with this drug, **AND**
- Patient must not receive more than 14 weeks of treatment under this restriction.

Treatment criteria:

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

Clinical criteria:

- The treatment must be initiated in combination with standard of care antibiotic.

The assessment of a patient's response to this initial course of treatment must be made after the third dose of vedolizumab so there is an adequate time for a response to be demonstrated. The assessment must be made prior to obtaining a PBS authority for continuing treatment from the dose at week 14. Where a response assessment is not conducted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

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

(a) details of the proposed prescription; 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) which includes the following:

(i) the patient's baseline Modified Pouchitis Disease Activity Index (mPDAI) score and endoscopic mPDAI subscore; and

(ii) details of prior drug therapy for this condition [dosage, date of commencement and duration of therapy].

The endoscopic assessment contributing to the Modified Pouchitis Disease Activity Index score to confirm the patient's condition at baseline must have been performed no more than 4 weeks prior to the application.

Applications for treatment of this condition must be received within 4 weeks of the endoscopy to confirm diagnosis.

The prescriber must exclude secondary causes of pouchitis, for example:

(a) Ischaemia;

(b) Crohn's disease (CD) or CD of the pouch;

(c) Irritable pouch syndrome;

(d) Predominant cuffitis;

(e) Pouch stricture or pouch fistula;

(f) Active infection;

(g) NSAIDs;

(h) Coeliac disease.

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

Moderate to severe chronic pouchitis

Treatment Phase: Initial 2 treatment (Recommencement of treatment after a break in biological medicine)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 14 weeks of treatment under this restriction.

Treatment criteria:

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

Clinical criteria:

- The treatment must be initiated in combination with standard of care antibiotic.

The assessment of a patient's response to this initial course of treatment must be made after the third dose of vedolizumab so there is adequate time for a response to be demonstrated. The assessment must be made prior to obtaining a PBS authority for continuing treatment from the dose at week 14.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond 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.

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

(a) details of the proposed prescription; 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) which includes the following:

(i) the patient's baseline Modified Pouchitis Disease Activity Index (mPDAI) score and minimum endoscopic mPDAI sub-score; and

(ii) details of prior biological medicine therapy for this condition, [date of commencement and duration of therapy].

The endoscopic assessment contributing to the Modified Pouchitis Disease Activity Index score to confirm the patient's condition at baseline must have been performed no more than 4 weeks prior to the application.

Applications for treatment of this condition must be received within 4 weeks of the endoscopy to confirm diagnosis.

The prescriber must exclude secondary causes of pouchitis, for example:

(a) Ischaemia;

(b) Crohn's disease (CD) or CD of the pouch;

(c) Irritable pouch syndrome;

(d) Predominant cuffitis;

(e) Pouch stricture or pouch fistula;

(f) Active infection;

(g) NSAIDs;

(h) Coeliac disease.

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

Moderate to severe chronic pouchitis

Treatment Phase: Balance of Supply - Initial 1 treatment (new patient) and Initial 2 treatment (recommencement of treatment after a break in biological medicine)

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 treatment (new patient) restriction to complete 14 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 treatment (recommencement of treatment after a break in biological medicine) to complete 14 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 14 weeks treatment available under the above treatment phases.

Treatment criteria:

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

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

Moderate to severe chronic pouchitis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received this drug as their most recent course of PBS-subsidised biological medicine for this condition, **AND**
- Patient must have demonstrated or sustained a partial or complete response, as determined by the treating clinician, to the most recent PBS-subsidised course of treatment with this drug for this condition.

Treatment criteria:

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

Patients who have failed to demonstrate a partial or complete response with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

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

An application for the continuing treatment must be made following the third dose with this drug and requested no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where an application is not made within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

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

Moderate to severe chronic pouchitis

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

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 December 2024, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- Patient must have undergone ileal pouch anal anastomosis (IPAA) due to ulcerative colitis at least one year prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be confirmed based on the patient's symptoms, treatment history and baseline endoscopic examination of the pouch (pouchoscopy), **AND**
- Patient must have had a Modified Pouchitis Disease Activity Index (mPDAI) score of at least 5 at the time of initiating treatment with this drug for this condition, **AND**
- Patient must have had a minimum endoscopic mPDAI sub-score of at least 2 at the time of initiating treatment with this drug for this condition, **AND**
- Patient must had at least 3 recurrent episodes of pouchitis within the year prior to initiating treatment with this drug for this condition, each of which was treated with at least 2 weeks of antibiotic or other prescription therapy; OR
- The condition must have required maintenance antibiotic therapy taken continuously for at least 4 weeks before commencing treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must have been initiated in combination with standard of care antibiotic, **AND**
- Patient must have demonstrated a partial or complete response to treatment with this drug as determined by the treating clinician, for this condition if the patient has received non-PBS-subsidised treatment for the first three doses of induction.

Treatment criteria:

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

The assessment of a patient's response to this course of treatment must be made after the third dose of vedolizumab so there is adequate time for a response to be demonstrated. The assessment must be made prior to obtaining a PBS authority for continuing treatment from the dose at week 14.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

The application for authorisation of treatment must be in writing and must include:

(a) details of the proposed prescription; 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) which includes the following:

(i) the patient's baseline Modified Pouchitis Disease Activity Index (mPDAI) score and minimum endoscopic mPDAI sub-score; and

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

(iii) the date of commencement of this drug for this condition.

The endoscopic assessment contributing to the Modified Pouchitis Disease Activity Index score to confirm the patient's condition at baseline must have been performed no more than 4 weeks prior to initiation with non-PBS-subsidised treatment with this drug.

The prescriber must have excluded secondary causes of pouchitis, for example:

(a) Ischaemia;

(b) Crohn's disease (CD) or CD of the pouch;

(c) Irritable pouch syndrome;

(d) Predominant cuffitis;

(e) Pouch stricture or pouch fistula;

(f) Active infection;

(g) NSAIDs;

(h) Coeliac disease.

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

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

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

vedolizumab 300 mg injection, 1 vial

14670D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	..	2949.93	Entyvio [TK]