



Australian Government

**Department of Health
and Aged Care**



Schedule of Pharmaceutical Benefits

Summary of Changes

Effective 1 March 2024



Fees, Patient Contributions and Safety Net Thresholds

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

Dispensing Fees:	Ready-prepared	\$8.37
	Dangerous drug fee	\$5.18
	Extemporaneously-prepared	\$10.41
	Allowable additional patient charge*	\$3.45
Additional Fees (for safety net prices):	Ready-prepared	\$1.40
	Extemporaneously-prepared	\$1.80
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 March 2024. The Schedule is updated on the first day of each month and is available on the internet at www.pbs.gov.au.

Prescriber Bag

Alterations

Alteration – Manufacturer Code

		From	To
13147Y	Paxlovid – NIRMATRELVIR (&) RITONAVIR , nirmatrelvir 150 mg tablet [4] (&) ritonavir 100 mg tablet [2], 5 x 6	HD	PF

General Pharmaceutical Benefits

Additions

Addition – Item

14078Y	ABIRATERONE (&) METHYLPREDNISOLONE , abiraterone acetate 125 mg tablet [120] (&) methylprednisolone 4 mg tablet [30], 1 pack (<i>Yonsa Mpred</i>)
13955L	ACARBOSE , acarbose 50 mg tablet, 90 (<i>Acarbose Mylan, Acarbose Viatris, GLYBOSAY</i>)
13869Y	ACARBOSE , acarbose 100 mg tablet, 90 (<i>Acarbose Viatris, GLYBOSAY</i>)
14003B	ALENDRONATE + COLECALCIFEROL , alendronate 70 mg + colecalciferol 70 microgram (2800 units) tablet, 4 (<i>Fosamax Plus</i>)
13835E	ALENDRONATE + COLECALCIFEROL , alendronate 70 mg + colecalciferol 140 microgram (5600 units) tablet, 4 (<i>Fosamax Plus 70 mg/140 mcg</i>)
13897K	ALOGLIPTIN , alogliptin 6.25 mg tablet, 28 (<i>Nesina</i>)
13977P	ALOGLIPTIN , alogliptin 12.5 mg tablet, 28 (<i>Nesina</i>)
13953J	ALOGLIPTIN , alogliptin 25 mg tablet, 28 (<i>Nesina</i>)
13989G	ALOGLIPTIN + METFORMIN , alogliptin 12.5 mg + metformin hydrochloride 1 g tablet, 56 (<i>Nesina Met 12.5/1000</i>)
14062D	ALOGLIPTIN + METFORMIN , alogliptin 12.5 mg + metformin hydrochloride 500 mg tablet, 56 (<i>Nesina Met 12.5/500</i>)
14061C	ALOGLIPTIN + METFORMIN , alogliptin 12.5 mg + metformin hydrochloride 850 mg tablet, 56 (<i>Nesina Met 12.5/850</i>)
13963X	AMLODIPINE + ATORVASTATIN , amlodipine 10 mg + atorvastatin 80 mg tablet, 30 (<i>Cadivast 10/80, Caduet 10/80</i>)
13858J	ANASTROZOLE , anastrozole 1 mg tablet, 30 (<i>APO-Anastrozole, Anastrozole GH, Anastrozole Sandoz, Arianna 1, Arimidex</i>)
13933H	BICARBONATE , sodium bicarbonate 840 mg capsule, 100 (<i>Sodibic</i>)
13979R	BROMOCRIPTINE , bromocriptine 2.5 mg tablet, 30 (<i>Parlodel</i>)
13901P	CABERGOLINE , cabergoline 500 microgram tablet, 8 (<i>Dostinex</i>)
14051M	CARBAMAZEPINE , carbamazepine 100 mg/5 mL oral liquid, 300 mL (<i>Tegretol Liquid</i>)
14050L	CARBAMAZEPINE , carbamazepine 200 mg modified release tablet, 200 (<i>Tegretol CR 200</i>)
13918M	CARBAMAZEPINE , carbamazepine 400 mg modified release tablet, 200 (<i>Tegretol CR 400</i>)
13967D	CARBIMAZOLE , carbimazole 5 mg tablet, 100 (<i>Neo-Mercazole, THIRAZOL, WP Carbimazole</i>)

13999T	CICLOSPORIN , ciclosporin 10 mg capsule, 60 (<i>Neoral 10</i>)
13883Q	CICLOSPORIN , ciclosporin 25 mg capsule, 30 (<i>APO-Ciclosporin, Cyclosporin Sandoz, Neoral 25</i>)
13910D	CICLOSPORIN , ciclosporin 50 mg capsule, 30 (<i>APO-Ciclosporin, Cyclosporin Sandoz, Neoral 50</i>)
13911E	CICLOSPORIN , ciclosporin 100 mg capsule, 30 (<i>APO-Ciclosporin, Cyclosporin Sandoz, Neoral 100</i>)
14001X	CICLOSPORIN , ciclosporin 100 mg/mL oral liquid, 50 mL (<i>Neoral</i>)
13946B	CORTISONE , cortisone acetate 5 mg tablet, 50 (<i>Cortate</i>)
13862N	CORTISONE , cortisone acetate 25 mg tablet, 60 (<i>Cortate</i>)
13925X	CYPROTERONE , cyproterone acetate 50 mg tablet, 20 (<i>ANTERONE 50, Cyproterone Sandoz, Pharmacor Cyproterone 50</i>)
14023C	CYPROTERONE , cyproterone acetate 50 mg tablet, 50 (<i>ANTERONE 50, Androcur, Cyproterone Sandoz, Pharmacor Cyproterone 50</i>)
14022B	CYPROTERONE , cyproterone acetate 100 mg tablet, 50 (<i>ANTERONE 100, Androcur-100, Cyproterone Sandoz, Pharmacor Cyproterone 100</i>)
13844P	DAPAGLIFLOZIN , dapagliflozin 10 mg tablet, 28 (<i>Forxiga</i>)
14054Q	DAPAGLIFLOZIN , dapagliflozin 10 mg tablet, 28 (<i>Forxiga</i>)
14073Q	DAPAGLIFLOZIN , dapagliflozin 10 mg tablet, 28 (<i>Forxiga</i>)
13851B	DAPAGLIFLOZIN + METFORMIN , dapagliflozin 5 mg + metformin hydrochloride 1 g modified release tablet, 56 (<i>Xigduo XR 5/1000</i>)
14028H	DAPAGLIFLOZIN + METFORMIN , dapagliflozin 10 mg + metformin hydrochloride 500 mg modified release tablet, 28 (<i>Xigduo XR 10/500</i>)
13875G	DAPAGLIFLOZIN + METFORMIN , dapagliflozin 10 mg + metformin hydrochloride 1 g modified release tablet, 28 (<i>Xigduo XR 10/1000</i>)
13889B	DESMOPRESSIN , desmopressin acetate 200 microgram tablet, 30 (<i>Minirin</i>)
13945Y	DESMOPRESSIN , desmopressin acetate 200 microgram tablet, 30 (<i>Minirin</i>)
14004C	DESMOPRESSIN , desmopressin 120 microgram sublingual wafer, 30 (<i>Minirin Melt</i>)
13890C	DESMOPRESSIN , desmopressin 240 microgram sublingual wafer, 30 (<i>Minirin Melt</i>)
14007F	DEXAMETHASONE , dexamethasone 500 microgram tablet, 30 (<i>Dexamethsone</i>)
13900N	DUTASTERIDE , dutasteride 500 microgram capsule, 30 (<i>APO-Dutasteride, Avodart</i>)
13929D	DUTASTERIDE + TAMSULOSIN , dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram modified release capsule, 30 (<i>Doubluts, Duodart 500ug/400ug</i>)
13845Q	EMPAGLIFLOZIN , empagliflozin 10 mg tablet, 30 (<i>Jardiance</i>)
14018T	EMPAGLIFLOZIN , empagliflozin 10 mg tablet, 30 (<i>Jardiance</i>)
13920P	EMPAGLIFLOZIN , empagliflozin 25 mg tablet, 30 (<i>Jardiance</i>)
13904T	EMPAGLIFLOZIN + LINAGLIPTIN , empagliflozin 10 mg + linagliptin 5 mg tablet, 30 (<i>Glyxambi</i>)
13958P	EMPAGLIFLOZIN + LINAGLIPTIN , empagliflozin 25 mg + linagliptin 5 mg tablet, 30 (<i>Glyxambi</i>)
13852C	EMPAGLIFLOZIN + METFORMIN , empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60 (<i>Jardiamet 5 mg/1000 mg</i>)
14029J	EMPAGLIFLOZIN + METFORMIN , empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60 (<i>Jardiamet 5 mg/500 mg</i>)
13987E	EMPAGLIFLOZIN + METFORMIN , empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60 (<i>Jardiamet 12.5 mg/1000 mg</i>)
13903R	EMPAGLIFLOZIN + METFORMIN , empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60 (<i>Jardiamet 12.5 mg/500 mg</i>)
13861M	EPROSARTAN , eprosartan 600 mg tablet, 28 (<i>Teveten</i>)
13912F	EPROSARTAN , eprosartan 600 mg tablet, 28 (<i>Teveten</i>)
14026F	ESTRADIOL , estradiol 0.1% (1 mg/g) gel, 28 x 1 g sachets (<i>Sandrena</i>)
13978Q	ESTRADIOL , estradiol 10 microgram modified release pessary, 18 (<i>Estro-Pess, Vagifem Low</i>)
13872D	ESTRADIOL , estradiol valerate 1 mg tablet, 56 (<i>Progynova</i>)

13931F **ESTRADIOL**, estradiol 2 mg tablet, 56 (*Zumenon*)

13980T **ESTRADIOL**, estradiol valerate 2 mg tablet, 56 (*Progynova*)

14024D **ESTRADIOL (&) ESTRADIOL + DYDROGESTERONE**, estradiol 1 mg tablet [14] (&) estradiol 1 mg + dydrogesterone 10 mg tablet [14], 28 (*Femoston 1/10*)

13930E **ESTRADIOL (&) ESTRADIOL + DYDROGESTERONE**, estradiol 2 mg tablet [14] (&) estradiol 2 mg + dydrogesterone 10 mg tablet [14], 28 (*Femoston 2/10*)

13902Q **ESTRADIOL + NORETHISTERONE ACETATE**, estradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch, 8 (*Estalis continuous 50/140*)

13926Y **ESTRIOL**, estriol 0.1% (1 mg/g) cream, 15 g (*Ovestin*)

14059Y **ESTRIOL**, estriol 500 microgram pessary, 15 (*Ovestin Ovula*)

14014N **ETHOSUXIMIDE**, ethosuximide 250 mg/5 mL oral liquid, 200 mL (*Zarontin*)

14040Y **EVEROLIMUS**, everolimus 750 microgram tablet, 60 (*Certican, Everocan*)

13941R **EVEROLIMUS**, everolimus 1 mg tablet, 60 (*Certican, Everocan*)

13857H **EXEMESTANE**, exemestane 25 mg tablet, 30 (*APO-Exemestane, Aromasin, Exemestane GH, Exemestane Sandoz*)

14036R **EXEMESTANE**, exemestane 25 mg tablet, 30 (*APO-Exemestane, Aromasin, Exemestane GH, Exemestane Sandoz*)

13868X **GLIBENCLAMIDE**, glibenclamide 5 mg tablet, 100 (*Daonil*)

13922R **GLICLAZIDE**, gliclazide 60 mg modified release tablet, 60 (*ARDIX GLICLAZIDE 60mg MR, Diamicon 60mg MR, Gliclazide Lupin MR, Pharmacor Gliclazide MR*)

13896J **GLICLAZIDE**, gliclazide 80 mg tablet, 100 (*APO-Gliclazide, APX-Gliclazide, Glyade, Nidem*)

13848W **GLIMEPIRIDE**, glimepiride 1 mg tablet, 30 (*Amaryl, Aylide 1, Glimepiride APOTEX, Glimepiride Sandoz*)

13870B **GLIMEPIRIDE**, glimepiride 2 mg tablet, 30 (*Aylide 2, Glimepiride APOTEX, Glimepiride Sandoz*)

14020X **GLIMEPIRIDE**, glimepiride 3 mg tablet, 30 (*Aylide 3, Glimepiride APOTEX, Glimepiride Sandoz*)

14055R **GLIMEPIRIDE**, glimepiride 4 mg tablet, 30 (*Aylide 4, Glimepiride APOTEX, Glimepiride Sandoz*)

14019W **GLIPIZIDE**, glipizide 5 mg tablet, 100 (*Melizide, Minidiab*)

13863P **HYDROCORTISONE**, hydrocortisone 4 mg tablet, 50 (*Hydrocortisone Viatrix 4, Hysone 4*)

14076W **HYDROMORPHONE**, hydromorphone hydrochloride 1 mg/mL oral liquid, 500 mL (*pms-HYDROMorphone*)

14080C **HYDROMORPHONE**, hydromorphone hydrochloride 1 mg/mL oral liquid, 500 mL (*pms-HYDROMorphone*)

14074R **IBRUTINIB**, ibrutinib 280 mg tablet, 30 (*Imbruvica*)

14079B **IBRUTINIB**, ibrutinib 280 mg tablet, 30 (*Imbruvica*)

14075T **IBRUTINIB**, ibrutinib 420 mg tablet, 30 (*Imbruvica*)

14085H **IBRUTINIB**, ibrutinib 420 mg tablet, 30 (*Imbruvica*)

14086J **IBRUTINIB**, ibrutinib 560 mg tablet, 30 (*Imbruvica*)

13887X **LABETALOL**, labetalol hydrochloride 100 mg tablet, 100 (*Presolol 100*)

14013M **LACOSAMIDE**, lacosamide 10 mg/mL oral liquid, 200 mL (*Vimpat*)

14048J **LACOSAMIDE**, lacosamide 10 mg/mL oral liquid, 200 mL (*Vimpat*)

14011K **LACOSAMIDE**, lacosamide 50 mg tablet, 14 (*Lacosam, Lacosamide ARX, Lacosamide Lupin, Lacosamide Sandoz, Vimcosa, Vimpat*)

14049K **LACOSAMIDE**, lacosamide 50 mg tablet, 14 (*Lacosam, Lacosamide ARX, Lacosamide Lupin, Lacosamide Sandoz, Vimcosa, Vimpat*)

13839J **LACOSAMIDE**, lacosamide 100 mg tablet, 56 (*Lacosam, Lacosamide ARX, Lacosamide Lupin, Lacosamide Sandoz, Vimcosa, Vimpat*)

13867W **LACOSAMIDE**, lacosamide 100 mg tablet, 56 (*Lacoress, Lacosam, Lacosamide ARX, Lacosamide Lupin, Lacosamide Sandoz, Vimcosa, Vimpat*)

13838H **LACOSAMIDE**, lacosamide 150 mg tablet, 56 (*Lacosam, Lacosamide ARX, Lacosamide Lupin, Lacosamide Sandoz, Vimcosa, Vimpat*)

14053P	LACOSAMIDE , lacosamide 150 mg tablet, 56 (<i>Lacoress, Lacosam, Lacosamide ARX, Lacosamide Lupin, Lacosamide Sandoz, Vimcosa, Vimpat</i>)
13949E	LACOSAMIDE , lacosamide 200 mg tablet, 56 (<i>Lacosam, Lacosamide ARX, Lacosamide Lupin, Lacosamide Sandoz, Vimcosa, Vimpat</i>)
13951G	LACOSAMIDE , lacosamide 200 mg tablet, 56 (<i>Lacoress, Lacosam, Lacosamide ARX, Lacosamide Lupin, Lacosamide Sandoz, Vimcosa, Vimpat</i>)
14047H	LAMOTRIGINE , lamotrigine 5 mg tablet, 56 (<i>Lamictal</i>)
13842M	LAMOTRIGINE , lamotrigine 25 mg tablet, 56 (<i>APX-Lamotrigine, LAMITAN, Lamictal, Lamotrigine GH, Logem, NOUMED LAMOTRIGINE, Reedos 25, Sandoz Lamotrigine</i>)
13975M	LAMOTRIGINE , lamotrigine 50 mg tablet, 56 (<i>APX-Lamotrigine, LAMITAN, Lamictal, Lamotrigine GH, Logem, NOUMED LAMOTRIGINE, Reedos 50, Sandoz Lamotrigine</i>)
14052N	LAMOTRIGINE , lamotrigine 100 mg tablet, 56 (<i>APX-Lamotrigine, LAMITAN, Lamictal, Lamotrigine GH, Logem, NOUMED LAMOTRIGINE, Reedos 100, Sandoz Lamotrigine</i>)
13843N	LAMOTRIGINE , lamotrigine 200 mg tablet, 56 (<i>APX-Lamotrigine, LAMITAN, Lamictal, Lamotrigine GH, Logem, NOUMED LAMOTRIGINE, Reedos 200, Sandoz Lamotrigine</i>)
14060B	LANTHANUM , lanthanum 500 mg chewable tablet, 2 x 45 (<i>Fosrenol</i>)
13986D	LANTHANUM , lanthanum 750 mg chewable tablet, 6 x 15 (<i>Fosrenol</i>)
13874F	LANTHANUM , lanthanum 1 g chewable tablet, 6 x 15 (<i>Fosrenol</i>)
13940Q	LEFLUNOMIDE , leflunomide 10 mg tablet, 30 (<i>Arabloc, Arava, Ataris 10, Leflunomide APOTEX, Leflunomide Sandoz, Leflunomide generichealth, Lunava 10</i>)
14068K	LEFLUNOMIDE , leflunomide 10 mg tablet, 30 (<i>Arabloc, Arava, Ataris 10, Leflunomide APOTEX, Leflunomide Sandoz, Leflunomide generichealth</i>)
13998R	LEFLUNOMIDE , leflunomide 20 mg tablet, 30 (<i>Arava, Ataris 20, Leflunomide APOTEX, Leflunomide Sandoz, Leflunomide generichealth</i>)
14069L	LEFLUNOMIDE , leflunomide 20 mg tablet, 30 (<i>Arava, Ataris 20, Leflunomide APOTEX, Leflunomide Sandoz, Leflunomide generichealth, Lunava 20</i>)
13939P	LETROZOLE , letrozole 2.5 mg tablet, 30 (<i>Femara 2.5 mg, Femolet, Gynotril, Letrozole APOTEX, Letrozole GH, Letrozole Sandoz, Pharmacor Letrozole 2.5</i>)
13993L	LEVETIRACETAM , levetiracetam 100 mg/mL oral liquid, 300 mL (<i>APO-Levetiracetam, Keppra, Kerron, Levetiracetam GH, Levetiracetam-AFT</i>)
13992K	LEVETIRACETAM , levetiracetam 250 mg tablet, 60 (<i>APO-Levetiracetam, Keppra, Kevtam 250, Levactam, Levetiracetam GH, Levetiracetam Mylan, Levetiracetam SZ, Levi 250, NOUMED LEVETIRACETAM</i>)
14034P	LEVETIRACETAM , levetiracetam 500 mg tablet, 60 (<i>APO-Levetiracetam, Keppra, Kevtam 500, Levactam, Levetiracetam GH, Levetiracetam Mylan, Levetiracetam SZ, Levi 500, NOUMED LEVETIRACETAM</i>)
13937M	LEVETIRACETAM , levetiracetam 1 g tablet, 60 (<i>APO-Levetiracetam, Keppra, Kevtam 1000, Levactam, Levetiracetam GH, Levetiracetam Mylan, Levetiracetam SZ, Levi 1000, NOUMED LEVETIRACETAM</i>)
13954K	LINAGLIPTIN , linagliptin 5 mg tablet, 30 (<i>Trajenta</i>)
13959Q	LINAGLIPTIN + METFORMIN , linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60 (<i>Trajentamet</i>)
14065G	LINAGLIPTIN + METFORMIN , linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60 (<i>Trajentamet</i>)
13879L	LINAGLIPTIN + METFORMIN , linagliptin 2.5 mg + metformin hydrochloride 1 g tablet, 60 (<i>Trajentamet</i>)
13966C	LIOTHYRONINE , liothyronine sodium 20 microgram tablet, 100 (<i>Tertroxin</i>)
13956M	MEDROXYPROGESTERONE , medroxyprogesterone acetate 5 mg tablet, 56 (<i>Provera, Ralovera</i>)
13849X	MEDROXYPROGESTERONE , medroxyprogesterone acetate 10 mg tablet, 30 (<i>Provera, Ralovera</i>)
13928C	MEDROXYPROGESTERONE , medroxyprogesterone acetate 10 mg tablet, 100 (<i>Provera, Ralovera</i>)
14067J	MEDROXYPROGESTERONE , medroxyprogesterone acetate 100 mg tablet, 100 (<i>Provera</i>)
13881N	MEDROXYPROGESTERONE , medroxyprogesterone acetate 200 mg tablet, 60 (<i>Provera</i>)
13961T	MEDROXYPROGESTERONE , medroxyprogesterone acetate 250 mg tablet, 60 (<i>Provera</i>)
14038W	MEDROXYPROGESTERONE , medroxyprogesterone acetate 500 mg tablet, 30 (<i>Provera</i>)
13899M	METFORMIN , metformin hydrochloride 500 mg modified release tablet, 120 (<i>APO-Metformin XR 500, Blooms the Chemist Metformin XR 500, Diabex XR 500, Metex XR, Pharmacor Metformin XR</i>)

13976N **METFORMIN**, metformin hydrochloride 500 mg tablet, 100 (*APX-Metformin, Blooms The Chemist Metformin 500 mg, Diabex, Diaformin, FORMET 500, Glucobete 500, Metformin GH, Metformin Sandoz*)

13952H **METFORMIN**, metformin hydrochloride 850 mg tablet, 60 (*APX-Metformin, Blooms The Chemist Metformin 850 mg, Diabex 850, Diaformin 850, FORMET 850, Glucobete 850, Metformin Sandoz*)

13847T **METFORMIN**, metformin hydrochloride 1 g modified release tablet, 60 (*APO-Metformin XR 1000, Blooms the Chemist Metformin XR 1000, Diabex XR 1000, Diaformin XR 1000, METEX XR, Pharmacor Metformin XR*)

14056T **METFORMIN**, metformin hydrochloride 1 g tablet, 90 (*APX-Metformin, Blooms The Chemist Metformin 1000 mg, Diabex 1000, Diaformin 1000, Formet 1000, Glucobete 1000, Metformin GH, Metformin Sandoz*)

14005D **METHENAMINE HIPPURATE**, methenamine hippurate 1 g tablet, 100 (*Hiprex, Uramet*)

13882P **METHOTREXATE**, methotrexate 50 mg/2 mL injection, 5 x 2 mL vials (*DBL Methotrexate*)

14041B **MINOXIDIL**, minoxidil 10 mg tablet, 100 (*Loniten*)

14077X **MORPHINE**, morphine hydrochloride trihydrate 10 mg/mL oral liquid, 20 mL (*Morphini HCl Streuli*)

14083F **MORPHINE**, morphine hydrochloride trihydrate 10 mg/mL oral liquid, 20 mL (*Morphini HCl Streuli*)

13884R **MYCOPHENOLATE**, mycophenolate mofetil 250 mg capsule, 100 (*APO-Mycophenolate, CellCept, Mycophenolate Sandoz, Pharmacor Mycophenolate 250*)

14037T **MYCOPHENOLATE**, mycophenolate mofetil 250 mg capsule, 50 (*Ceptolate*)

14071N **MYCOPHENOLATE**, mycophenolate mofetil 1 g/5 mL powder for oral liquid, 165 mL (*CellCept, Pharmacor Mycophenolate*)

13856G **MYCOPHENOLATE**, mycophenolate 180 mg enteric tablet, 120 (*Mycophenolic Acid ARX, Myfortic*)

13938N **MYCOPHENOLATE**, mycophenolate 360 mg enteric tablet, 120 (*MYCOTEX, Mycophenolic Acid ARX, Myfortic*)

14000W **MYCOPHENOLATE**, mycophenolate mofetil 500 mg tablet, 50 (*CellCept, Ceptolate, MycoCept, Mycophenolate APOTEX, Mycophenolate GH, Mycophenolate Sandoz, Noumed Mycophenolate, Pharmacor Mycophenolate 500*)

13873E **NORETHISTERONE**, norethisterone 5 mg tablet, 30 (*Primolut N*)

13932G **NORETHISTERONE ACETATE + ESTRADIOL (&) ESTRADIOL**, estradiol 50 microgram/24 hours patch [4] (& estradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch [4], 8 (*Estalis sequi 50/140*))

13981W **NORETHISTERONE ACETATE + ESTRADIOL (&) ESTRADIOL**, estradiol 50 microgram/24 hours patch [4] (& estradiol 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch [4], 8 (*Estalis sequi 50/250*))

13964Y **OLMESARTAN + AMLODIPINE**, olmesartan medoxomil 40 mg + amlodipine 5 mg tablet, 30 (*OLMEKAR, Olmesartan/Amlodipine - MYL 40/5, Olmesartan/Amlodipine 40/5 APOTEX, Olmesartan/Amlodipine Sandoz, Pharmacor Olmesartan Amlodipine 40/5, Sevikar 40/5*)

13943W **OLMESARTAN + AMLODIPINE**, olmesartan medoxomil 40 mg + amlodipine 10 mg tablet, 30 (*OLMEKAR, Olmesartan/Amlodipine - MYL 40/10, Olmesartan/Amlodipine 40/10 APOTEX, Olmesartan/Amlodipine Sandoz, Pharmacor Olmesartan Amlodipine 40/10, Sevikar 40/10*)

14002Y **OLMESARTAN + AMLODIPINE + HYDROCHLOROTHIAZIDE**, olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 25 mg tablet, 30 (*APO-Olmesartan/Amlodipine/HCTZ 40/10/25, Olamlo HCT 40/10/25, Olmekar HCT 40/10/25, Sevikar HCT 40/10/25*)

13936L **OXCARBAZEPINE**, oxcarbazepine 60 mg/mL oral liquid, 250 mL (*Trileptal*)

14033N **OXCARBAZEPINE**, oxcarbazepine 300 mg tablet, 100 (*Trileptal*)

13935K **OXCARBAZEPINE**, oxcarbazepine 600 mg tablet, 100 (*Trileptal*)

13984B **OXYBUTYNIN**, oxybutynin 3.9 mg/24 hours patch, 8 (*Oxytrol*)

13957N **OXYBUTYNIN**, oxybutynin hydrochloride 5 mg tablet, 100 (*Ditropan*)

13864Q **PERAMPANEL**, perampanel 4 mg tablet, 28 (*Fycompa*)

13948D **PERAMPANEL**, perampanel 4 mg tablet, 28 (*Fycompa*)

14010J **PERAMPANEL**, perampanel 6 mg tablet, 28 (*Fycompa*)

14046G **PERAMPANEL**, perampanel 6 mg tablet, 28 (*Fycompa*)

13915J **PERAMPANEL**, perampanel 8 mg tablet, 28 (*Fycompa*)

13970G **PERAMPANEL**, perampanel 8 mg tablet, 28 (*Fycompa*)

13914H **PERAMPANEL**, perampanel 10 mg tablet, 28 (*Fycompa*)

13971H	PERAMPANEL , perampanel 10 mg tablet, 28 (<i>Fycompa</i>)
13865R	PERAMPANEL , perampanel 12 mg tablet, 28 (<i>Fycompa</i>)
14012L	PERAMPANEL , perampanel 12 mg tablet, 28 (<i>Fycompa</i>)
13968E	PHENOXYMETHYLPENICILLIN , phenoxymethylpenicillin 250 mg capsule, 50 (<i>Cilicaine VK, LPV</i>)
14044E	PHENOXYMETHYLPENICILLIN , phenoxymethylpenicillin 250 mg tablet, 25 (<i>Aspecillin VK</i>)
14015P	PHENYTOIN , phenytoin sodium 30 mg capsule, 200 (<i>Dilantin Sodium</i>)
13972J	PHENYTOIN , phenytoin sodium 100 mg capsule, 200 (<i>Dilantin Sodium</i>)
13841L	PHENYTOIN , phenytoin 30 mg/5 mL oral liquid, 500 mL (<i>Dilantin</i>)
13894G	PHENYTOIN , phenytoin 50 mg chewable tablet, 200 (<i>Dilantin Infatabs</i>)
13850Y	PHOSPHORUS , phosphorus 500 mg effervescent tablet, 100 (<i>PHOSPHATE PHEBRA</i>)
13898L	PIOGLITAZONE , pioglitazone 15 mg tablet, 28 (<i>APOTEX-Pioglitazone, Acpio 15, Actaze, Actos, Vexazone</i>)
13921Q	PIOGLITAZONE , pioglitazone 30 mg tablet, 28 (<i>APOTEX-Pioglitazone, Acpio 30, Actaze, Actos, NOUMED PIOGLITAZONE, Pioglitazone Sandoz, Vexazone</i>)
14057W	PIOGLITAZONE , pioglitazone 45 mg tablet, 28 (<i>APOTEX-Pioglitazone, Acpio 45, Actaze, Actos, NOUMED PIOGLITAZONE, Pioglitazone Sandoz, Vexazone</i>)
13866T	PIZOTIFEN , pizotifen 500 microgram tablet, 100 (<i>Sandomigran 0.5</i>)
13888Y	PREDNISOLONE , prednisolone 1 mg tablet, 100 (<i>Panafcortelone, Predsolone</i>)
14045F	PREDNISOLONE , prednisolone 5 mg tablet, 60 (<i>Panafcortelone, Solone</i>)
13837G	PREDNISOLONE SODIUM PHOSPHATE , prednisolone (as sodium phosphate) 5 mg/mL oral liquid, 30 mL (<i>PredMix, Redipred</i>)
14043D	PREDNISONE , prednisone 1 mg tablet, 100 (<i>Panafcort, Predsone</i>)
13944X	PREDNISONE , prednisone 5 mg tablet, 60 (<i>Panafcort, Sone</i>)
13942T	PROBENECID , probenecid 500 mg tablet, 100 (<i>Pro-Cid</i>)
13927B	PROPANTHELINE , propantheline bromide 15 mg tablet, 100 (<i>Pro-Banthine</i>)
13836F	PROPYLTHIOURACIL , propylthiouracil 50 mg tablet, 100 (<i>PTU</i>)
13982X	QUINAGOLIDE , quinagolide 75 microgram tablet, 30 (<i>Norprolac</i>)
13895H	SAXAGLIPTIN , saxagliptin 2.5 mg tablet, 28 (<i>Onglyza</i>)
13923T	SAXAGLIPTIN , saxagliptin 5 mg tablet, 28 (<i>Onglyza</i>)
13855F	SAXAGLIPTIN + DAPAGLIFLOZIN , saxagliptin 5 mg + dapagliflozin 10 mg tablet, 28 (<i>Qtern 5/10</i>)
13880M	SAXAGLIPTIN + METFORMIN , saxagliptin 2.5 mg + metformin hydrochloride 1 g modified release tablet, 56 (<i>Kombiglyze XR 2.5/1000</i>)
14030K	SAXAGLIPTIN + METFORMIN , saxagliptin 5 mg + metformin hydrochloride 500 mg modified release tablet, 28 (<i>Kombiglyze XR 5/500</i>)
13876H	SAXAGLIPTIN + METFORMIN , saxagliptin 5 mg + metformin hydrochloride 1 g modified release tablet, 28 (<i>Kombiglyze XR 5/1000</i>)
13934J	SEVELAMER , sevelamer hydrochloride 800 mg tablet, 180 (<i>Renagel</i>)
14027G	SEVELAMER , sevelamer carbonate 800 mg tablet, 180 (<i>Sevelamer Apotex, Sevelamer Lupin</i>)
13885T	SIROLIMUS , sirolimus 1 mg/mL oral liquid, 60 mL (<i>Rapamune</i>)
13860L	SIROLIMUS , sirolimus 500 microgram tablet, 100 (<i>Rapamune</i>)
14072P	SIROLIMUS , sirolimus 1 mg tablet, 100 (<i>Rapamune</i>)
13886W	SIROLIMUS , sirolimus 2 mg tablet, 100 (<i>Rapamune</i>)
14021Y	SITAGLIPTIN , sitagliptin 25 mg tablet, 28 (<i>Januvia, Sitagliptin Lupin, Sitagliptin SUN, Sitagliptin Sandoz Pharma, Sitaglo, Xelevia</i>)
14058X	SITAGLIPTIN , sitagliptin 50 mg tablet, 28 (<i>Januvia, Sitagliptin Lupin, Sitagliptin SUN, Sitagliptin Sandoz Pharma, Sitaglo, Xelevia</i>)
13871C	SITAGLIPTIN , sitagliptin 100 mg tablet, 28 (<i>Januvia, Sitagliptin Lupin, Sitagliptin SUN, Sitagliptin Sandoz Pharma, Sitaglo, Xelevia</i>)

13994M **SITAGLIPTIN + METFORMIN**, sitagliptin 50 mg + metformin hydrochloride 500 mg tablet, 56 (*Janumet, SITAGLIPTIN/METFORMIN 50/500 SUN, Sitagliptin/Metformin Sandoz, Velmetia*)

14064F **SITAGLIPTIN + METFORMIN**, sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56 (*Janumet, SITAGLIPTIN/METFORMIN 50/850 SUN, Sitagliptin/Metformin Sandoz, Velmetia*)

13990H **SITAGLIPTIN + METFORMIN**, sitagliptin 50 mg + metformin hydrochloride 1 g modified release tablet, 56 (*Janumet XR, Sitagliptin/Metformin Sandoz XR*)

14035Q **SITAGLIPTIN + METFORMIN**, sitagliptin 50 mg + metformin hydrochloride 1 g tablet, 56 (*Janumet, SITAGLIPTIN/METFORMIN 50/1000 SUN, Sitagliptin/Metformin Sandoz, Velmetia*)

14031L **SITAGLIPTIN + METFORMIN**, sitagliptin 100 mg + metformin hydrochloride 1 g tablet: modified release, 28 (*Janumet XR, Sitagliptin/Metformin Sandoz XR*)

14042C **SPIRONOLACTONE**, spironolactone 100 mg tablet, 100 (*Aldactone, Spiractin 100, Spironolactone Viatrix 100*)

13985C **SUCROFERRIC OXYHYDROXIDE**, sucroferric oxyhydroxide 2.5 g (iron 500 mg) chewable tablet, 90 (*Velphoro*)

13916K **SULTHIAME**, sulthiame 50 mg tablet, 200 (*Ospolot*)

14016Q **SULTHIAME**, sulthiame 200 mg tablet, 200 (*Ospolot*)

13907Y **TACROLIMUS**, tacrolimus 500 microgram modified release capsule, 30 (*ADVAGRAF XL*)

13908B **TACROLIMUS**, tacrolimus 500 microgram capsule, 100 (*Pacrolim, Pharmacor Tacrolimus 0.5, Prograf, Tacrograf, Tacrolimus Sandoz*)

14066H **TACROLIMUS**, tacrolimus 750 microgram capsule, 100 (*Tacrolimus Sandoz*)

13962W **TACROLIMUS**, tacrolimus 1 mg modified release capsule, 60 (*ADVAGRAF XL*)

14070M **TACROLIMUS**, tacrolimus 1 mg capsule, 100 (*Pacrolim, Pharmacor Tacrolimus 1, Prograf, Tacrograf, Tacrolimus Sandoz*)

13995N **TACROLIMUS**, tacrolimus 2 mg capsule, 100 (*Tacrolimus Sandoz*)

13996P **TACROLIMUS**, tacrolimus 3 mg modified release capsule, 50 (*ADVAGRAF XL*)

13909C **TACROLIMUS**, tacrolimus 5 mg capsule, 50 (*Pharmacor Tacrolimus 5, Prograf, Tacrograf, Tacrolimus Sandoz*)

14039X **TACROLIMUS**, tacrolimus 5 mg modified release capsule, 30 (*ADVAGRAF XL*)

13906X **TAMOXIFEN**, tamoxifen 20 mg tablet, 30 (*Genox 20, Nolvadex-D*)

13960R **TAMOXIFEN**, tamoxifen 20 mg tablet, 30 (*Nolvadex-D*)

13997Q **TAMOXIFEN**, tamoxifen 20 mg tablet, 60 (*GenRx Tamoxifen, Genox 20, Tamosin, Tamoxifen Sandoz*)

13891D **TERIPARATIDE**, teriparatide 250 microgram/mL injection, 2.4 mL cartridge (*Terrosa*)

13924W **TESTOSTERONE**, testosterone 1% (12.5 mg/actuation) gel, 2 x 60 actuations (*Testogel*)

14025E **TESTOSTERONE**, testosterone 2% (23 mg/actuation) gel, 56 actuations (*Testavan*)

13983Y **TESTOSTERONE**, testosterone 1% (50 mg/5 g) gel, 30 x 5 g sachets (*Testogel*)

13892E **TIAGABINE**, tiagabine 5 mg tablet, 50 (*Gabitril*)

13947C **TIAGABINE**, tiagabine 10 mg tablet, 50 (*Gabitril*)

13893F **TIAGABINE**, tiagabine 15 mg tablet, 50 (*Gabitril*)

13965B **TOBRAMYCIN**, tobramycin 28 mg powder for inhalation, 224 capsules (*TOBI podhaler*)

14006E **TOBRAMYCIN**, tobramycin 300 mg/5 mL inhalation solution, 56 x 5 mL ampoules (*TOBRAMYCIN SUN, Tobi, Tobramycin WKT*)

14063E **TOPIRAMATE**, topiramate 15 mg capsule, 60 (*Topamax Sprinkle*)

13905W **TOPIRAMATE**, topiramate 25 mg capsule, 60 (*Topamax Sprinkle*)

13878K **TOPIRAMATE**, topiramate 50 mg capsule, 60 (*Topamax Sprinkle*)

13969F **TOPIRAMATE**, topiramate 25 mg tablet, 60 (*APO-Topiramate, Epiramax 25, NOUMED TOPIRAMATE, RBX Topiramate, Tamate, Topamax, Topiramate Sandoz*)

13913G **TOPIRAMATE**, topiramate 50 mg tablet, 60 (*APO-Topiramate, Epiramax 50, NOUMED TOPIRAMATE, RBX Topiramate, Tamate, Topamax, Topiramate Sandoz*)

14008G **TOPIRAMATE**, topiramate 100 mg tablet, 60 (*APO-Topiramate, Epiramax 100, NOUMED TOPIRAMATE, RBX Topiramate, Tamate, Topamax, Topiramate Sandoz*)

14009H	TOPIRAMATE , topiramate 200 mg tablet, 60 (<i>APO-Topiramate, Epiramax 200, NOUMED TOPIRAMATE, RBX Topiramate, Tamate, Topamax, Topiramate Sandoz</i>)
13859K	TOREMIFENE , toremifene 60 mg tablet, 30 (<i>Fareston</i>)
13950F	VALPROATE , valproate sodium 200 mg/5 mL oral liquid, 300 mL (<i>Epilim Syrup</i>)
13973K	VALPROATE , valproate sodium 200 mg/5 mL oral liquid, 300 mL (<i>Epilim Liquid</i>)
13840K	VALPROATE , valproate sodium 100 mg tablet, 100 (<i>Epilim</i>)
14017R	VALPROATE , valproate sodium 200 mg enteric tablet, 100 (<i>Epilim EC, Sodium Valproate Sandoz, Valprease 200, Valpro EC 200, Valproate Winthrop EC 200</i>)
13917L	VALPROATE , valproate sodium 500 mg enteric tablet, 100 (<i>Epilim EC, Sodium Valproate Sandoz, Valprease 500, Valpro EC 500, Valproate Winthrop EC 500</i>)
13974L	VIGABATRIN , vigabatrin 500 mg powder for oral liquid, 60 sachets (<i>Sabril</i>)
13919N	VIGABATRIN , vigabatrin 500 mg tablet, 100 (<i>Sabril</i>)
13846R	VILDAGLIPTIN , vildagliptin 50 mg tablet, 60 (<i>Galvus</i>)
13877J	VILDAGLIPTIN + METFORMIN , vildagliptin 50 mg + metformin hydrochloride 500 mg tablet, 60 (<i>Galvumet 50/500</i>)
13991J	VILDAGLIPTIN + METFORMIN , vildagliptin 50 mg + metformin hydrochloride 850 mg tablet, 60 (<i>Galvumet 50/850</i>)
14032M	VILDAGLIPTIN + METFORMIN , vildagliptin 50 mg + metformin hydrochloride 1 g tablet, 60 (<i>Galvumet 50/1000</i>)
13853D	ZONISAMIDE , zonisamide 25 mg capsule, 56 (<i>Zonegran</i>)
13988F	ZONISAMIDE , zonisamide 50 mg capsule, 56 (<i>Zonegran</i>)
13854E	ZONISAMIDE , zonisamide 100 mg capsule, 56 (<i>Zonegran</i>)

Addition – Brand

8700X	<i>Blooms Escitalopram, BG</i> – ESCITALOPRAM , escitalopram 10 mg tablet, 28
9432K	<i>Blooms Escitalopram, BG</i> – ESCITALOPRAM , escitalopram 10 mg tablet, 28
8701Y	<i>Blooms Escitalopram, BG</i> – ESCITALOPRAM , escitalopram 20 mg tablet, 28
9433L	<i>Blooms Escitalopram, BG</i> – ESCITALOPRAM , escitalopram 20 mg tablet, 28
13587D	<i>BTC Fenofibrate, BG</i> – FENOFIBRATE , fenofibrate 145 mg tablet, 30
9023X	<i>BTC Fenofibrate, BG</i> – FENOFIBRATE , fenofibrate 145 mg tablet, 30
13411W	<i>Lercan, RW</i> – LERCANIDIPINE , lercanidipine hydrochloride 10 mg tablet, 28
8534E	<i>Lercan, RW</i> – LERCANIDIPINE , lercanidipine hydrochloride 10 mg tablet, 28
13412X	<i>Lercan, RW</i> – LERCANIDIPINE , lercanidipine hydrochloride 20 mg tablet, 28
8679T	<i>Lercan, RW</i> – LERCANIDIPINE , lercanidipine hydrochloride 20 mg tablet, 28
8816B	<i>Modafinil Viatris, AL</i> – MODAFINIL , modafinil 100 mg tablet, 60
8399C	<i>BTC Pantoprazole, BG</i> – PANTOPRAZOLE , pantoprazole 20 mg enteric tablet, 30
11681T	<i>BTC Pantoprazole, BG</i> – PANTOPRAZOLE , pantoprazole 40 mg enteric tablet, 30
12277E	<i>BTC Pantoprazole, BG</i> – PANTOPRAZOLE , pantoprazole 40 mg enteric tablet, 30
8007K	<i>BTC Pantoprazole, BG</i> – PANTOPRAZOLE , pantoprazole 40 mg enteric tablet, 30
8008L	<i>BTC Pantoprazole, BG</i> – PANTOPRAZOLE , pantoprazole 40 mg enteric tablet, 30
9393J	<i>Simpral, AF</i> – PRAMIPEXOLE , pramipexole dihydrochloride monohydrate 125 microgram tablet, 30
9394K	<i>Simpral, AF</i> – PRAMIPEXOLE , pramipexole dihydrochloride monohydrate 250 microgram tablet, 100
8456C	<i>Blooms The Chemist Quetiapine, BG</i> – QUETIAPINE , quetiapine 25 mg tablet, 60
8457D	<i>APX-QUETIAPINE, TX</i> – QUETIAPINE , quetiapine 100 mg tablet, 90
8457D	<i>Blooms The Chemist Quetiapine, BG</i> – QUETIAPINE , quetiapine 100 mg tablet, 90
8458E	<i>Blooms The Chemist Quetiapine, BG</i> – QUETIAPINE , quetiapine 200 mg tablet, 60
8580N	<i>Blooms The Chemist Quetiapine, BG</i> – QUETIAPINE , quetiapine 300 mg tablet, 60

Addition – Equivalence Indicator

- 2124T *Ordine 10, MF* – **MORPHINE**, morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL
5239R *Ordine 10, MF* – **MORPHINE**, morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL

Addition – Note

- 2124T **MORPHINE**, morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL (*Ordine 10*)
5239R **MORPHINE**, morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL (*Ordine 10*)
12996B **NIRMATRELVIR (&) RITONAVIR**, nirmatrelvir 150 mg tablet [4] (&) ritonavir 100 mg tablet [2], 5 x 6 (*Paxlovid*)

Deletions

Deletion – Brand

- 13529C *Atorvastatin GH, GQ* – **ATORVASTATIN**, atorvastatin 20 mg tablet, 30
8214H *Atorvastatin GH, GQ* – **ATORVASTATIN**, atorvastatin 20 mg tablet, 30
13419G *Bisoprolol Dr.Reddy's, RI* – **BISOPROLOL**, bisoprolol fumarate 2.5 mg tablet, 28
8604W *Bisoprolol Dr.Reddy's, RI* – **BISOPROLOL**, bisoprolol fumarate 2.5 mg tablet, 28
13443M *Bisoprolol Dr.Reddy's, RI* – **BISOPROLOL**, bisoprolol fumarate 5 mg tablet, 28
8605X *Bisoprolol Dr.Reddy's, RI* – **BISOPROLOL**, bisoprolol fumarate 5 mg tablet, 28
13444N *Bisoprolol Dr.Reddy's, RI* – **BISOPROLOL**, bisoprolol fumarate 10 mg tablet, 28
8606Y *Bisoprolol Dr.Reddy's, RI* – **BISOPROLOL**, bisoprolol fumarate 10 mg tablet, 28
9157Y *Cinacalcet Mylan, AF* – **CINACALCET**, cinacalcet 30 mg tablet, 28
13365K *Clopidogrel GH, GQ* – **CLOPIDOGREL**, clopidogrel 75 mg tablet, 28
9354H *Clopidogrel GH, GQ* – **CLOPIDOGREL**, clopidogrel 75 mg tablet, 28
13385L *EZESIM 10/10, RZ* – **EZETIMIBE + SIMVASTATIN**, ezetimibe 10 mg + simvastatin 10 mg tablet, 30
9483D *EZESIM 10/10, RZ* – **EZETIMIBE + SIMVASTATIN**, ezetimibe 10 mg + simvastatin 10 mg tablet, 30
13442L *EZESIM 10/20, RZ* – **EZETIMIBE + SIMVASTATIN**, ezetimibe 10 mg + simvastatin 20 mg tablet, 30
9484E *EZESIM 10/20, RZ* – **EZETIMIBE + SIMVASTATIN**, ezetimibe 10 mg + simvastatin 20 mg tablet, 30
13535J *EZESIM 10/40, RZ* – **EZETIMIBE + SIMVASTATIN**, ezetimibe 10 mg + simvastatin 40 mg tablet, 30
8881K *EZESIM 10/40, RZ* – **EZETIMIBE + SIMVASTATIN**, ezetimibe 10 mg + simvastatin 40 mg tablet, 30
13595M *EZESIM 10/80, RZ* – **EZETIMIBE + SIMVASTATIN**, ezetimibe 10 mg + simvastatin 80 mg tablet, 30
8882L *EZESIM 10/80, RZ* – **EZETIMIBE + SIMVASTATIN**, ezetimibe 10 mg + simvastatin 80 mg tablet, 30
8654L *Levetacetam 250, RZ* – **LEVETIRACETAM**, levetiracetam 250 mg tablet, 60
8655M *Levetacetam 500, RZ* – **LEVETIRACETAM**, levetiracetam 500 mg tablet, 60
8656N *Levetacetam 1000, RZ* – **LEVETIRACETAM**, levetiracetam 1 g tablet, 60
2622B *Oxycodone Mylan, AL* – **OXYCODONE**, oxycodone hydrochloride 5 mg tablet, 20
5195K *Oxycodone Mylan, AL* – **OXYCODONE**, oxycodone hydrochloride 5 mg tablet, 20
13437F *Telmisartan-DRLA, RZ* – **TELMISARTAN**, telmisartan 40 mg tablet, 28
8355R *Telmisartan-DRLA, RZ* – **TELMISARTAN**, telmisartan 40 mg tablet, 28
13593K *Telmisartan-DRLA, RZ* – **TELMISARTAN**, telmisartan 80 mg tablet, 28
8356T *Telmisartan-DRLA, RZ* – **TELMISARTAN**, telmisartan 80 mg tablet, 28

Alterations

Alteration – Authorised Prescriber

		<i>From</i>	<i>To</i>
2396D	METHOTREXATE , methotrexate 5 mg/2 mL injection, 5 x 2 mL vials (<i>DBL Methotrexate</i>)	M	M,N
11275K	METHOTREXATE , methotrexate 7.5 mg/0.15 mL injection, 0.15 mL syringe (<i>Trexject</i>)	M	M,N
11283W	METHOTREXATE , methotrexate 10 mg/0.2 mL injection, 0.2 mL syringe (<i>Trexject</i>)	M	M,N
11268C	METHOTREXATE , methotrexate 15 mg/0.3 mL injection, 0.3 mL syringe (<i>Trexject</i>)	M	M,N
11288D	METHOTREXATE , methotrexate 20 mg/0.4 mL injection, 0.4 mL syringe (<i>Trexject</i>)	M	M,N

11295L	METHOTREXATE , methotrexate 25 mg/0.5 mL injection, 0.5 mL syringe (<i>Trexject</i>)	M	M,N
2395C	METHOTREXATE , methotrexate 50 mg/2 mL injection, 5 x 2 mL vials (<i>DBL Methotrexate</i>)	M	M,N
1622J	METHOTREXATE , methotrexate 2.5 mg tablet, 30 (<i>Chexate, Methoblastin</i>)	M	M,N
1623K	METHOTREXATE , methotrexate 10 mg tablet, 50 (<i>Chexate, Methoblastin</i>)	M	M,N
2272N	METHOTREXATE , methotrexate 10 mg tablet, 15 (<i>Methoblastin</i>)	M	M,N

Alteration – Note

2698B	ABIRATERONE , abiraterone acetate 250 mg tablet, 120 (<i>Zytiga</i>)		
11206T	ABIRATERONE , abiraterone acetate 500 mg tablet, 60 (<i>Zytiga</i>)		
13263C	ABIRATERONE (&) METHYLPREDNISOLONE , abiraterone acetate 125 mg tablet [120] (&) methylprednisolone 4 mg tablet [60], 1 pack (<i>Yonsa Mpred</i>)		
12992T	APALUTAMIDE , apalutamide 60 mg tablet, 120 (<i>Erlyard</i>)		
13288J	APALUTAMIDE , apalutamide 60 mg tablet, 120 (<i>Erlyard</i>)		
12684N	DAROLUTAMIDE , darolutamide 300 mg tablet, 112 (<i>Nubeqa</i>)		
13769Q	DAROLUTAMIDE , darolutamide 300 mg tablet, 112 (<i>Nubeqa</i>)		
10174L	ENZALUTAMIDE , enzalutamide 40 mg capsule, 112 (<i>Xtandi</i>)		
13118K	ENZALUTAMIDE , enzalutamide 40 mg capsule, 112 (<i>Xtandi</i>)		
13353T	ENZALUTAMIDE , enzalutamide 40 mg capsule, 112 (<i>Xtandi</i>)		
11419B	IBRUTINIB , ibrutinib 140 mg capsule, 120 (<i>Imbruvica</i>)		
12910L	MOLNUPIRAVIR , molnupiravir 200 mg capsule, 40 (<i>Lagevrio</i>)		
12921C	OLAPARIB , olaparib 100 mg tablet, 56 (<i>Lynparza</i>)		
12932P	OLAPARIB , olaparib 100 mg tablet, 56 (<i>Lynparza</i>)		
12913P	OLAPARIB , olaparib 150 mg tablet, 56 (<i>Lynparza</i>)		
12929L	OLAPARIB , olaparib 150 mg tablet, 56 (<i>Lynparza</i>)		

Alteration – Restriction

12823X	DAPAGLIFLOZIN , dapagliflozin 10 mg tablet, 28 (<i>Forxiga</i>)		
12918X	EMPAGLIFLOZIN , empagliflozin 10 mg tablet, 30 (<i>Jardiance</i>)		
12910L	MOLNUPIRAVIR , molnupiravir 200 mg capsule, 40 (<i>Lagevrio</i>)		
12996B	NIRMATRELVIR (&) RITONAVIR , nirmatrelvir 150 mg tablet [4] (&) ritonavir 100 mg tablet [2], 5 x 6 (<i>Paxlovid</i>)		

Alteration – Manufacturer Code

		From	To
10800K	<i>Diprosone</i> – BETAMETHASONE DIPROPIONATE , betamethasone (as dipropionate) 0.05% cream, 15 g	OQ	AF
10800K	<i>Eleuphrat</i> – BETAMETHASONE DIPROPIONATE , betamethasone (as dipropionate) 0.05% cream, 15 g	OV	AL
10801L	<i>Diprosone</i> – BETAMETHASONE DIPROPIONATE , betamethasone (as dipropionate) 0.05% cream, 15 g	OQ	AF
10801L	<i>Eleuphrat</i> – BETAMETHASONE DIPROPIONATE , betamethasone (as dipropionate) 0.05% cream, 15 g	OV	AL
10802M	<i>Diprosone</i> – BETAMETHASONE DIPROPIONATE , betamethasone (as dipropionate) 0.05% cream, 15 g	OQ	AF
10802M	<i>Eleuphrat</i> – BETAMETHASONE DIPROPIONATE , betamethasone (as dipropionate) 0.05% cream, 15 g	OV	AL
10813D	<i>Diprosone</i> – BETAMETHASONE DIPROPIONATE , betamethasone (as dipropionate) 0.05% cream, 15 g	OQ	AF
10813D	<i>Eleuphrat</i> – BETAMETHASONE DIPROPIONATE , betamethasone (as dipropionate) 0.05% cream, 15 g	OV	AL
10824Q	<i>Diprosone</i> – BETAMETHASONE DIPROPIONATE , betamethasone (as dipropionate) 0.05% cream, 15 g	OQ	AF

10824Q	<i>Eleuphrat</i> – BETAMETHASONE DIPROPIONATE , betamethasone (as dipropionate) 0.05% cream, 15 g	OV	AL
1115Q	<i>Diprosone</i> – BETAMETHASONE DIPROPIONATE , betamethasone (as dipropionate) 0.05% cream, 15 g	OQ	AF
1115Q	<i>Eleuphrat</i> – BETAMETHASONE DIPROPIONATE , betamethasone (as dipropionate) 0.05% cream, 15 g	OV	AL
10795E	<i>Diprosone</i> – BETAMETHASONE DIPROPIONATE , betamethasone (as dipropionate) 0.05% ointment, 15 g	OQ	AF
10795E	<i>Eleuphrat</i> – BETAMETHASONE DIPROPIONATE , betamethasone (as dipropionate) 0.05% ointment, 15 g	OV	AL
10816G	<i>Diprosone</i> – BETAMETHASONE DIPROPIONATE , betamethasone (as dipropionate) 0.05% ointment, 15 g	OQ	AF
10816G	<i>Eleuphrat</i> – BETAMETHASONE DIPROPIONATE , betamethasone (as dipropionate) 0.05% ointment, 15 g	OV	AL
10820L	<i>Diprosone</i> – BETAMETHASONE DIPROPIONATE , betamethasone (as dipropionate) 0.05% ointment, 15 g	OQ	AF
10820L	<i>Eleuphrat</i> – BETAMETHASONE DIPROPIONATE , betamethasone (as dipropionate) 0.05% ointment, 15 g	OV	AL
10821M	<i>Diprosone</i> – BETAMETHASONE DIPROPIONATE , betamethasone (as dipropionate) 0.05% ointment, 15 g	OQ	AF
10821M	<i>Eleuphrat</i> – BETAMETHASONE DIPROPIONATE , betamethasone (as dipropionate) 0.05% ointment, 15 g	OV	AL
10823P	<i>Diprosone</i> – BETAMETHASONE DIPROPIONATE , betamethasone (as dipropionate) 0.05% ointment, 15 g	OQ	AF
10823P	<i>Eleuphrat</i> – BETAMETHASONE DIPROPIONATE , betamethasone (as dipropionate) 0.05% ointment, 15 g	OV	AL
1119X	<i>Diprosone</i> – BETAMETHASONE DIPROPIONATE , betamethasone (as dipropionate) 0.05% ointment, 15 g	OQ	AF
1119X	<i>Eleuphrat</i> – BETAMETHASONE DIPROPIONATE , betamethasone (as dipropionate) 0.05% ointment, 15 g	OV	AL
2812B	<i>Antroquoril</i> – BETAMETHASONE VALERATE , betamethasone (as valerate) 0.02% cream, 100 g	OV	AL
2812B	<i>Celestone-M</i> – BETAMETHASONE VALERATE , betamethasone (as valerate) 0.02% cream, 100 g	OQ	AF
12996B	<i>Paxlovid</i> – NIRMATRELVIR (&) RITONAVIR , nirmatrelvir 150 mg tablet [4] (&) ritonavir 100 mg tablet [2], 5 x 6	HD	PF
3054R	<i>Lyclear</i> – PERMETHRIN , permethrin 5% cream, 30 g	JT	ON

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>

Supply Only Commencing 1 March 2024

2639X	<i>HCU cooler 10, VF</i> – AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE , amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 87 mL sachets
9133Q	<i>HCU cooler 15, VF</i> – AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE , amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 130 mL pouches
3444G	<i>MMA/PA gel, VF</i> – AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, THREONINE AND VALINE AND LOW IN ISOLEUCINE , amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine powder for oral liquid, 30 x 24 g sachets
2674R	<i>TYR cooler 10, VF</i> – AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE , amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 87 mL pouches

9132P	<i>TYR cooler 15, VF</i> – AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE , amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 130 mL pouches
8667E	<i>TYR express 15, VF</i> – AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE , amino acid formula with vitamins and minerals without phenylalanine and tyrosine powder for oral liquid, 30 x 25 g sachets
2651M	<i>MSUD cooler 10, VF</i> – AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE , amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 87 mL pouches

Advance Notices

1 April 2024

Deletion – Brand

1299J	<i>Fenac 25, AF</i> – DICLOFENAC , diclofenac sodium 25 mg enteric tablet, 50
1300K	<i>Fenac, AF</i> – DICLOFENAC , diclofenac sodium 50 mg enteric tablet, 50
5076E	<i>Fenac 25, AF</i> – DICLOFENAC , diclofenac sodium 25 mg enteric tablet, 50
5077F	<i>Fenac, AF</i> – DICLOFENAC , diclofenac sodium 50 mg enteric tablet, 50
10780J	<i>Eryc, YN</i> – ERYTHROMYCIN , erythromycin 250 mg enteric capsule, 25
1404X	<i>Eryc, YN</i> – ERYTHROMYCIN , erythromycin 250 mg enteric capsule, 25
3325B	<i>Eryc, YN</i> – ERYTHROMYCIN , erythromycin 250 mg enteric capsule, 25
8125P	<i>Climara 50, BN</i> – ESTRADIOL , estradiol 50 microgram/24 hours patch, 4
8126Q	<i>Climara 100, BN</i> – ESTRADIOL , estradiol 100 microgram/24 hours patch, 4
8485N	<i>Climara 25, BN</i> – ESTRADIOL , estradiol 25 microgram/24 hours patch, 4
8486P	<i>Climara 75, BN</i> – ESTRADIOL , estradiol 75 microgram/24 hours patch, 4
13848W	<i>Aylide 1, AF</i> – GLIMEPIRIDE , glimepiride 1 mg tablet, 30
13870B	<i>Aylide 2, AF</i> – GLIMEPIRIDE , glimepiride 2 mg tablet, 30
14020X	<i>Aylide 3, AF</i> – GLIMEPIRIDE , glimepiride 3 mg tablet, 30
14055R	<i>Aylide 4, AF</i> – GLIMEPIRIDE , glimepiride 4 mg tablet, 30
8450R	<i>Aylide 1, AF</i> – GLIMEPIRIDE , glimepiride 1 mg tablet, 30
8451T	<i>Aylide 2, AF</i> – GLIMEPIRIDE , glimepiride 2 mg tablet, 30
8452W	<i>Aylide 4, AF</i> – GLIMEPIRIDE , glimepiride 4 mg tablet, 30
8533D	<i>Aylide 3, AF</i> – GLIMEPIRIDE , glimepiride 3 mg tablet, 30
10526B	<i>Ardix Lurasidone, RX</i> – LURASIDONE , lurasidone hydrochloride 40 mg tablet, 30
10529E	<i>Ardix Lurasidone, RX</i> – LURASIDONE , lurasidone hydrochloride 80 mg tablet, 30
5263B	<i>Methylpred, AL</i> – METHYLPREDNISOLONE , methylprednisolone 40 mg injection, 5 vials
12053J	<i>MS Contin Suspension 200 mg, MF</i> – MORPHINE , morphine sulfate pentahydrate 200 mg modified release granules, 28 sachets
8146R	<i>MS Contin Suspension 30 mg, MF</i> – MORPHINE , morphine sulfate pentahydrate 30 mg modified release granules, 28 sachets
8305D	<i>MS Contin Suspension 60 mg, MF</i> – MORPHINE , morphine sulfate pentahydrate 60 mg modified release granules, 28 sachets
8306E	<i>MS Contin Suspension 100 mg, MF</i> – MORPHINE , morphine sulfate pentahydrate 100 mg modified release granules, 28 sachets
8454Y	<i>MS Contin Suspension 200 mg, MF</i> – MORPHINE , morphine sulfate pentahydrate 200 mg modified release granules, 28 sachets
8490W	<i>MS Contin Suspension 20 mg, MF</i> – MORPHINE , morphine sulfate pentahydrate 20 mg modified release granules, 28 sachets
2335X	<i>Pregabalin GH, GQ</i> – PREGABALIN , pregabalin 75 mg capsule, 56
2355Y	<i>Pregabalin GH, GQ</i> – PREGABALIN , pregabalin 150 mg capsule, 56
2893G	<i>Stemzine, AV</i> – PROCHLORPERAZINE , prochlorperazine maleate 5 mg tablet, 25

5205Y	<i>Stemzine, AV</i> – PROCHLORPERAZINE , prochlorperazine maleate 5 mg tablet, 25
2167C	<i>VitA-POS, AE</i> – RETINOL PALMITATE + PARAFFIN , retinol palmitate 0.0138% + paraffin eye ointment, 5 g
2202X	<i>VitA-POS, AE</i> – RETINOL PALMITATE + PARAFFIN , retinol palmitate 0.0138% + paraffin eye ointment, 5 g
2222Y	<i>VitA-POS, AE</i> – RETINOL PALMITATE + PARAFFIN , retinol palmitate 0.0138% + paraffin eye ointment, 5 g
11877D	<i>Risperidone generichealth, GQ</i> – RISPERIDONE , risperidone 1 mg tablet, 60
11879F	<i>Risperidone generichealth, GQ</i> – RISPERIDONE , risperidone 1 mg tablet, 60
3169T	<i>Risperidone generichealth, GQ</i> – RISPERIDONE , risperidone 1 mg tablet, 60
3170W	<i>Risperidone generichealth, GQ</i> – RISPERIDONE , risperidone 2 mg tablet, 60
3171X	<i>Risperidone generichealth, GQ</i> – RISPERIDONE , risperidone 3 mg tablet, 60
8789N	<i>Risperidone generichealth, GQ</i> – RISPERIDONE , risperidone 1 mg tablet, 60
9079W	<i>Risperidone generichealth, GQ</i> – RISPERIDONE , risperidone 2 mg tablet, 60
2746M	<i>Tropisetron-AFT, AE</i> – TROPISETRON , tropisetron 5 mg/5 mL injection, 5 mL ampoule
10198R	<i>Vfend, PF</i> – VORICONAZOLE , voriconazole 200 mg tablet, 56
9364W	<i>Vfend, PF</i> – VORICONAZOLE , voriconazole 200 mg tablet, 56

1 May 2024

Deletion – Brand

5502N	<i>Poly Gel, AQ</i> – CARBOMER-974P , carbomer-974P 0.3% eye gel, 30 x 500 mg ampoules
8514D	<i>Poly Gel, AQ</i> – CARBOMER-974P , carbomer-974P 0.3% eye gel, 30 x 500 mg ampoules
5521N	<i>Bion Tears, AQ</i> – DEXTRAN-70 + HYPROMELLOSE , dextran-70 0.1% + hypromellose 0.3% eye drops, 28 x 0.4 mL ampoules
8299T	<i>Bion Tears, AQ</i> – DEXTRAN-70 + HYPROMELLOSE , dextran-70 0.1% + hypromellose 0.3% eye drops, 28 x 0.4 mL ampoules
1438Q	<i>Flarex, NV</i> – FLUOROMETHOLONE ACETATE , fluorometholone acetate 0.1% eye drops, 5 mL
5533F	<i>Flarex, NV</i> – FLUOROMETHOLONE ACETATE , fluorometholone acetate 0.1% eye drops, 5 mL
11296M	<i>Tenofovir Disoproxil Emtricitabine Mylan 300/200, AF</i> – TENOFOVIR DISOPROXIL + EMTRICITABINE , tenofovir disoproxil maleate 300 mg + emtricitabine 200 mg tablet, 30
10785P	<i>Trimethoprim Mylan, AL</i> – TRIMETHOPRIM , trimethoprim 300 mg tablet, 7
2666H	<i>Trimethoprim Mylan, AL</i> – TRIMETHOPRIM , trimethoprim 300 mg tablet, 7
2922T	<i>Trimethoprim Mylan, AL</i> – TRIMETHOPRIM , trimethoprim 300 mg tablet, 7

1 June 2024

Deletion – Brand

12114N	<i>Ceftriaxone Alphapharm, AF</i> – CEFTRIAZONE , ceftriaxone 1 g injection, 10 vials
1788D	<i>Ceftriaxone Alphapharm, AF</i> – CEFTRIAZONE , ceftriaxone 1 g injection, 5 vials
1357K	<i>Dosulepin Mylan, AL</i> – DOSULEPIN (DOTHIEPIN) , dosulepin (dothiepin) hydrochloride 25 mg capsule, 50

Palliative Care

Additions

Addition – Item

14084G	HYDROMORPHONE , hydromorphone hydrochloride 1 mg/mL oral liquid, 500 mL (<i>pms-HYDROMORPHONE</i>)
14081D	MORPHINE , morphine hydrochloride trihydrate 10 mg/mL oral liquid, 20 mL (<i>Morphini HCl Streuli</i>)

Addition – Equivalence Indicator

12472K	<i>Ordine 10, MF</i> – MORPHINE , morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL
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Addition – Note

12472K	MORPHINE , morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL (<i>Ordine 10</i>)
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Advance Notices

1 April 2024

Deletion – Brand

- 12488G *MS Contin Suspension 30 mg, MF – MORPHINE*, morphine sulfate pentahydrate 30 mg modified release granules, 28 sachets
- 12495P *MS Contin Suspension 100 mg, MF – MORPHINE*, morphine sulfate pentahydrate 100 mg modified release granules, 28 sachets
- 12505E *MS Contin Suspension 200 mg, MF – MORPHINE*, morphine sulfate pentahydrate 200 mg modified release granules, 28 sachets
- 12528J *MS Contin Suspension 20 mg, MF – MORPHINE*, morphine sulfate pentahydrate 20 mg modified release granules, 28 sachets
- 12536T *MS Contin Suspension 60 mg, MF – MORPHINE*, morphine sulfate pentahydrate 60 mg modified release granules, 28 sachets

Highly Specialised Drugs Program (Private Hospital)

Deletions

Deletion – Brand

- 11891W *Cinacalcet Mylan, AF – CINACALCET*, cinacalcet 30 mg tablet, 28
- 9625N *Cinacalcet Mylan, AF – CINACALCET*, cinacalcet 30 mg tablet, 28

Alterations

Alteration – Note

- 2747N **FILGRASTIM**, filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes (*Zarzio*)
- 6291D **FILGRASTIM**, filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes (*Nivestim*)
- 2733W **FILGRASTIM**, filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes (*Zarzio*)
- 6292E **FILGRASTIM**, filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes (*Nivestim*)
- 12176W **NUSINERSEN**, nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial (*Spinraza*)

Alteration – Restriction

- 12176W **NUSINERSEN**, nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial (*Spinraza*)

Advance Notices

1 June 2024

Deletion – Brand

- 12201E *Ambrisentan Mylan, AF – AMBRISENTAN*, ambrisentan 5 mg tablet, 30
- 9648T *Ambrisentan Mylan, AF – AMBRISENTAN*, ambrisentan 5 mg tablet, 30

Highly Specialised Drugs Program (Public Hospital)

Deletions

Deletion – Brand

- 11887P *Cinacalcet Mylan, AF – CINACALCET*, cinacalcet 30 mg tablet, 28
- 5621W *Cinacalcet Mylan, AF – CINACALCET*, cinacalcet 30 mg tablet, 28

Alterations

Alteration – Note

- 2758E **FILGRASTIM**, filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes (*Zarzio*)
- 5742F **FILGRASTIM**, filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes (*Nivestim*)
- 2783L **FILGRASTIM**, filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes (*Zarzio*)
- 5744H **FILGRASTIM**, filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes (*Nivestim*)
- 12177X **NUSINERSEN**, nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial (*Spinraza*)

Alteration – Restriction

- 12177X **NUSINERSEN**, nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial (*Spinraza*)

Advance Notices

1 June 2024

Deletion – Brand

12212R *Ambrisentan Mylan, AF* – **AMBRISENTAN**, ambrisentan 5 mg tablet, 30

5607D *Ambrisentan Mylan, AF* – **AMBRISENTAN**, ambrisentan 5 mg tablet, 30

Highly Specialised Drugs Program (Community Access)

Additions

Addition – Brand

10353X *Entecavir Viatris, AL* – **ENTECAVIR**, entecavir 1 mg tablet, 30

Advance Notices

1 April 2024

Deletion – Brand

10305J *Trizivir, VI* – **ABACAVIR + LAMIVUDINE + ZIDOVUDINE**, abacavir 300 mg + lamivudine 150 mg + zidovudine 300 mg tablet, 60

10337C *Telzir, VI* – **FOSAMPRENAVIR**, fosamprenavir 700 mg tablet, 60

10285H *Kaletra, VE* – **LOPINA VIR + RITONAVIR**, lopinavir 100 mg + ritonavir 25 mg tablet, 60

1 May 2024

Deletion – Brand

11149T *Tenofovir Disoproxil Emtricitabine Mylan 300/200, AF* – **TENOFOVIR DISOPROXIL + EMTRICITABINE**, tenofovir disoproxil maleate 300 mg + emtricitabine 200 mg tablet, 30

1 June 2024

Deletion – Brand

10284G *Lamivudine 150 mg + Zidovudine 300 mg Alphapharm, AF* – **LAMIVUDINE + ZIDOVUDINE**, lamivudine 150 mg + zidovudine 300 mg tablet, 60

Growth Hormone Program

Advance Notices

1 April 2024

Deletion – Brand

10438J *NutropinAq, IS* – **SOMATROPIN**, somatropin 10 mg/2 mL injection, 2 mL cartridge

10478L *NutropinAq, IS* – **SOMATROPIN**, somatropin 10 mg/2 mL injection, 2 mL cartridge

11650E *NutropinAq, IS* – **SOMATROPIN**, somatropin 10 mg/2 mL injection, 2 mL cartridge

9604L *NutropinAq, IS* – **SOMATROPIN**, somatropin 10 mg/2 mL injection, 2 mL cartridge

Repatriation Pharmaceutical Benefits

Deletions

Deletion – Brand

10169F *Clopidogrel GH, GQ* – **CLOPIDOGREL**, clopidogrel 75 mg tablet, 28

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>

Supply Only Commencing 1 March 2024

10850C *Arginaid. NT* – **PROTEIN FORMULA WITH ARGININE, VITAMIN C AND E**, protein formula with arginine, vitamin C and E powder for oral liquid, 14 x 9.2 g sachets

13020G *Arginaid Extra, NT* – **PROTEIN FORMULA WITH ARGININE, VITAMIN C, E AND ZINC**, protein formula with arginine, vitamin C, E and zinc oral liquid, 24 x 237 mL cartons

Prescriber Bag

▪ MOLNUPIRAVIR

molnupiravir 200 mg capsule, 40

13144T	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	2	*2192.27	Lagevrio [MK]

OR

▪ NIRMATRELVIR (&) RITONAVIR

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

13147Y	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
NP	2	*2216.27	Paxlovid [PF]

General Pharmaceutical Benefits

▪ ABIRATERONE

Caution The bioavailability on a mg to mg basis of abiraterone combination product and abiraterone single drug product is not equivalent. When changing between abiraterone products, exercise caution in explaining correct dosing directions to the patient.

Note Special Pricing Arrangements apply.

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

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

Authority required

Castration resistant metastatic carcinoma of the prostate

Clinical criteria:

- The treatment must be used in combination with a corticosteroid, **AND**
- The treatment must not be used in combination with chemotherapy, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must not be a PBS benefit where disease progression occurs whilst being treated with any of: (i) a combination treatment containing the individual drugs in one pharmaceutical benefit, (ii) the individual drugs obtained as separate pharmaceutical benefits, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.

abiraterone acetate 500 mg tablet, 60

11206T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3442.99	31.60	Zytiga [JC]

abiraterone acetate 250 mg tablet, 120

2698B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3442.99	31.60	Zytiga [JC]

▪ ABIRATERONE (&) METHYLPREDNISOLONE

Caution The bioavailability on a mg to mg basis of abiraterone combination product and abiraterone single drug product is not equivalent. When changing between abiraterone products, exercise caution in explaining correct dosing directions to the patient.

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

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

Authority required

Castration resistant metastatic carcinoma of the prostate

Clinical criteria:

- The treatment must not be used in combination with chemotherapy, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must not be a PBS benefit where disease progression occurs whilst being treated with any of: (i) a combination treatment containing the individual drugs in one pharmaceutical benefit, (ii) the individual drugs obtained as separate pharmaceutical benefits, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.

abiraterone acetate 125 mg tablet [120] (&) methylprednisolone 4 mg tablet [60], 1 pack

13263C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
	‡1	2	..	1359.77	31.60	Yonsa Mpred [RA]	

▀ ABIRATERONE (&) METHYLPREDNISOLONE

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

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

Metastatic castration sensitive carcinoma of the prostate

Clinical criteria:

- The treatment must be/have been initiated within 6 months of treatment initiation with androgen deprivation therapy, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

Treatment criteria:

- Patient must be undergoing concurrent androgen deprivation therapy.

abiraterone acetate 125 mg tablet [120] (&) methylprednisolone 4 mg tablet [30], 1 pack

14078Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
	‡1	5	..	1144.67	31.60	Yonsa Mpred [RA]	

▀ ACARBOSE**Restricted benefit**

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

acarbose 50 mg tablet, 90

13955L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	2	5	..	*41.97	31.60	^a Acarbose Mylan [AF] ^a GLYBOSAY [RW]	^a Acarbose Viatris [AL]

acarbose 100 mg tablet, 90

13869Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	2	5	..	*54.05	31.60	^a Acarbose Viatris [AL]	^a GLYBOSAY [RW]

▀ ALENDRONATE + COLECALCIFEROL

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Authority required (STREAMLINED)

15032

Corticosteroid-induced osteoporosis

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 currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

14898

Osteoporosis

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 aged 70 years or older.

Clinical criteria:

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

14993

Established osteoporosis

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 fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

alendronate 70 mg + colecalciferol 140 microgram (5600 units) tablet, 4

13835E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*24.03	25.43	Fosamax Plus 70 mg/140 mcg [MQ]

▪ ALENDRONATE + COLECALCIFEROL

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Note Fosamax Plus provides a supplemental intake of vitamin D. The amount of colecalciferol present in Fosamax Plus is not sufficient to use as the sole treatment for correction of vitamin D deficiency.

Authority required (STREAMLINED)

15024

Corticosteroid-induced osteoporosis

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 currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

15011

Osteoporosis

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 aged 70 years or older.

Clinical criteria:

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

15035

Established osteoporosis

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 fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

alendronate 70 mg + colecalciferol 70 microgram (2800 units) tablet, 4

14003B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*24.03	25.43	Fosamax Plus [MQ]

■ ALOGLIPTIN

Note Alogliptin is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

Authority required (STREAMLINED)

14862

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; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, 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 despite treatment with either metformin or a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with alogliptin.

alogliptin 6.25 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13897K	2	5	..	*103.57	31.60	Nesina [TK]

NP

alogliptin 12.5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13977P	2	5	..	*103.57	31.60	Nesina [TK]

NP

alogliptin 25 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13953J	2	5	..	*103.57	31.60	Nesina [TK]

NP

■ ALOGLIPTIN + METFORMIN

Note This fixed dose combination tablet is not PBS-subsidised for use in combination with a sulfonylurea (triple oral therapy), as initial therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

Authority required (STREAMLINED)

14876

Diabetes mellitus type 2

Treatment Phase: Continuing

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 previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and alogliptin.

alogliptin 12.5 mg + metformin hydrochloride 1 g tablet, 56

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13989G	2	5	..	*109.39	31.60	Nesina Met 12.5/1000 [TK]

NP

alogliptin 12.5 mg + metformin hydrochloride 500 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14062D	2	5	..	*106.57	31.60	Nesina Met 12.5/500 [TK]

NP

alogliptin 12.5 mg + metformin hydrochloride 850 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14061C	2	5	..	*108.57	31.60	Nesina Met 12.5/850 [TK]

NP

■ AMLODIPINE + ATORVASTATIN

Restricted benefit

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

amlodipine 10 mg + atorvastatin 80 mg tablet, 30

13963X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*25.23	26.63	^a Cadivast 10/80 [AF]
			^B 10.00	*35.23	26.63	^a Caduet 10/80 [AS]

■ ANASTROZOLE

Note This drug is not PBS-subsidised for primary prevention of breast cancer.

Note This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer where the total duration of this drug (or any other aromatase inhibitor) treatment extends beyond 5 years.

Note Shared Care Model:

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

Restricted benefit

Breast cancer

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 hormone receptor positive.

anastrozole 1 mg tablet, 30

13858J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*32.85	31.60	^a Anastrozole GH [GQ]	^a Anastrozole Sandoz [SZ]
						^a APO-Anastrozole [TX]	^a Arianna 1 [AF]
			^B 8.10	*40.95	31.60	^a Arimidex [AP]	

■ APALUTAMIDE

Note Special Pricing Arrangements apply.

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

Authority required

Castration resistant non-metastatic carcinoma of the prostate

Clinical criteria:

- The condition must have evidence of an absence of distant metastases on the most recently performed conventional medical imaging used to evaluate the condition, **AND**
- The condition must be associated with a prostate-specific antigen level that was observed to have at least doubled in value in a time period of within 10 months anytime prior to first commencing treatment with this drug, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.

Treatment criteria:

- Patient must be undergoing concurrent treatment with androgen deprivation therapy.

Prescribing instructions:

Retain the results of all investigative imaging and prostate-specific antigen (PSA) level measurements on the patient's medical records - do not submit copies of these with this authority application.

The PSA level doubling time must be based on at least three PSA levels obtained within a time period of 10 months any time prior to first commencing a novel hormonal drug for this condition. The third reading is to demonstrate that the doubling was durable and must be at least 1 week apart from the second reading.

apalutamide 60 mg tablet, 120

12992T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3715.43	31.60	Erlyand [JC]

■ APALUTAMIDE

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

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

Metastatic castration sensitive carcinoma of the prostate

Clinical criteria:

- The treatment must be/have been initiated within 6 months of treatment initiation with androgen deprivation therapy, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

Treatment criteria:

- Patient must be undergoing concurrent androgen deprivation therapy.


apalutamide 60 mg tablet, 120

13288J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3715.43	31.60	Erlyand [JC]

■ BICARBONATE**Restricted benefit**

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

sodium bicarbonate 840 mg capsule, 100

13933H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*29.37	30.77	Sodibic [AS]

■ BROMOCRIPTINE**Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.**Restricted benefit**

Acromegaly

Clinical criteria:

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

Restricted benefit

Parkinson disease

Clinical criteria:

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

Restricted benefit

Pathological hyperprolactinaemia

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 be one in whom surgery is not indicated.

Restricted benefit

Pathological hyperprolactinaemia

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 had surgery for this condition with incomplete resolution.

Restricted benefit

Pathological hyperprolactinaemia

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 be one in whom radiotherapy is not indicated.

Restricted benefit

Pathological hyperprolactinaemia

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 had radiotherapy for this condition with incomplete resolution.

bromocriptine 2.5 mg tablet, 30

13979R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*51.53	31.60	Parlodel [SZ]

▪ CABERGOLINE

Restricted benefit

Pathological hyperprolactinaemia

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 be one in whom surgery is not indicated.

Restricted benefit

Pathological hyperprolactinaemia

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 had surgery for this condition with incomplete resolution.

Restricted benefit

Pathological hyperprolactinaemia

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 be one in whom radiotherapy is not indicated.

Restricted benefit

Pathological hyperprolactinaemia

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 had radiotherapy for this condition with incomplete resolution.

cabergoline 500 microgram tablet, 8

13901P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*120.25	31.60	Dostinex [PF]

▪ 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.

Restricted benefit

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

carbamazepine 100 mg/5 mL oral liquid, 300 mL

14051M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*38.95	31.60	Tegretol Liquid [NV]

carbamazepine 200 mg modified release tablet, 200

14050L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*48.55	31.60	Tegretol CR 200 [NV]

carbamazepine 400 mg modified release tablet, 200

13918M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*80.55	31.60	Tegretol CR 400 [NV]

▪ CARBIMAZOLE

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.

carbimazole 5 mg tablet, 100

13967D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	2	..	*54.37	31.60	^a Neo-Mercazole [GH]	^a THIRAZOL [NB]
						^a WP Carbimazole [TN]	

▪ CICLOSPORIN

Caution Careful monitoring of patients is mandatory.

Restricted benefit

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

ciclosporin 10 mg capsule, 60

13999T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	3	..	*176.01	31.60	Neoral 10 [NV]

ciclosporin 100 mg capsule, 30

13911E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	3	..	*560.49	31.60	^a APO-Ciclosporin [TX] ^a Neoral 100 [NV]	^a Cyclosporin Sandoz [SZ]

ciclosporin 25 mg capsule, 30

13883Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	3	..	*138.33	31.60	^a APO-Ciclosporin [TX] ^a Neoral 25 [NV]	^a Cyclosporin Sandoz [SZ]

ciclosporin 50 mg capsule, 30

13910D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	3	..	*279.17	31.60	^a APO-Ciclosporin [TX] ^a Neoral 50 [NV]	^a Cyclosporin Sandoz [SZ]

ciclosporin 100 mg/mL oral liquid, 50 mL

14001X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	3	..	*1391.17	31.60	Neoral [NV]

■ CORTISONE


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.

cortisone acetate 25 mg tablet, 60

13862N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	4	..	*37.91	31.60	Cortate [AS]

cortisone acetate 5 mg tablet, 50

13946B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	4	..	*27.65	29.05	Cortate [AS]

■ CYPROTERONE

Restricted benefit

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

cyproterone acetate 50 mg tablet, 50

14023C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*136.93	31.60	^a ANTERONE 50 [RW] ^a Pharmacor Cyproterone 50 [CR]	^a Cyproterone Sandoz [HX]
			^B 4.12	*141.05	31.60	^a Androcur [BN]	

cyproterone acetate 100 mg tablet, 50

14022B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*108.61	31.60	^a ANTERONE 100 [RW] ^a Pharmacor Cyproterone 100 [CR]	^a Cyproterone Sandoz [HX]
			^B 2.42	*111.03	31.60	^a Androcur-100 [BN]	

■ CYPROTERONE

Caution This drug should not be used during pregnancy as it may result in feminisation of the male foetus.

Authority required (STREAMLINED)

14868

Moderate to severe androgenisation

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 not be indicated by acne alone, as this is not a sufficient indication of androgenisation.

Population criteria:

- Patient must be female.

Clinical criteria:

- Patient must not be pregnant.

cyproterone acetate 50 mg tablet, 20

13925X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*37.55	31.60	^a ANTERONE 50 [RW] ^a Pharmacor Cyproterone 50 [CR]	^a Cyproterone Sandoz [HX]

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

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

Authority required (STREAMLINED)**15047**

Chronic heart failure

Clinical criteria:

- Patient must be symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.

dapagliflozin 10 mg tablet, 28

12823X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	57.82	31.60	Forxiga [AP]

NP

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

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


Authority required (STREAMLINED)**15051**

Chronic heart failure

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 be symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.

dapagliflozin 10 mg tablet, 28

14054Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*102.65	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 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)**14471**

Chronic heart failure

Clinical criteria:

- Patient must be symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of greater than 40%, **AND**
- Patient must have documented evidence of structural changes in the heart on echocardiography that would be expected to cause diastolic dysfunction (e.g. left ventricular hypertrophy), **AND**
- Patient must have documented evidence of at least one of the following: (i) diastolic dysfunction with high filling pressure on echocardiography, stress echocardiography or cardiac catheterisation; (ii) hospitalisation for heart failure in the 12 months prior to initiating treatment with this drug; (iii) requirement for intravenous diuretic therapy in the 12 months prior to initiating treatment with this drug; (iv) elevated N-terminal pro brain natriuretic peptide (NT-proBNP) levels in the absence of another cause, **AND**
- Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.

dapagliflozin 10 mg tablet, 28

14073Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	57.82	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.

Authority required (STREAMLINED)**14905**

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; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, 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 despite treatment with either metformin or a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with a gliptin and an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1.

Authority required (STREAMLINED)**14974**

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 insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, 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 prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1.

Authority required (STREAMLINED)

14949

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, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, 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 prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1.

Note PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

Authority required (STREAMLINED)

14859

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

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, **AND**
- The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1 analogue.

Note PBS-subsidised dual oral therapy does not include combination use of: a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or

- an SGLT2 inhibitor with a glitazone.

dapagliflozin 10 mg tablet, 28

13844P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*102.65	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.

Authority required (STREAMLINED)

14987

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

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 previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and dapagliflozin.

Note This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

Authority required (STREAMLINED)

14878

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 a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, 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 prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

Note This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

Note PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

Authority required (STREAMLINED)

14881

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 insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, 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 prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

Note This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

Authority required (STREAMLINED)

14924

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

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 a dipeptidyl peptidase 4 inhibitor (gliptin), **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

Note This fixed dose combination is not PBS-subsidised for initiating dual oral combination treatment or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, or another SGLT2 inhibitor.


Note PBS-subsidised dual oral therapy does not include combination use of: a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.


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

13851B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*108.47	31.60	Xigduo XR 5/1000 [AP]

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

13875G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*105.65	31.60	Xigduo XR 10/1000 [AP]

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

14028H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*104.15	31.60	Xigduo XR 10/500 [AP]

▪ **DAROLUTAMIDE**

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

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

Note Special Pricing Arrangements apply.

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

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

Castration resistant non-metastatic carcinoma of the prostate

Clinical criteria:

- The condition must have evidence of an absence of distant metastases on the most recently performed conventional medical imaging used to evaluate the condition, **AND**
- The condition must be associated with a prostate-specific antigen level that was observed to have at least doubled in value in a time period of within 10 months anytime prior to first commencing treatment with this drug, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.

Treatment criteria:

- Patient must be undergoing concurrent treatment with androgen deprivation therapy.

Prescribing instructions:

Retain the results of all investigative imaging and prostate-specific antigen (PSA) level measurements on the patient's medical records - do not submit copies of these with this authority application.

The PSA level doubling time must be based on at least three PSA levels obtained within a time period of 10 months any time prior to first commencing a novel hormonal drug for this condition. The third reading is to demonstrate that the doubling was durable and must be at least 1 week apart from the second reading.

darolutamide 300 mg tablet, 112

12684N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3537.77	31.60	Nubeqa [BN]

▪ DAROLUTAMIDE

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

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

Metastatic castration sensitive carcinoma of the prostate

Clinical criteria:

- The treatment must be/have been initiated within 6 months of treatment initiation with androgen deprivation therapy, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

Treatment criteria:

- Patient must be undergoing concurrent androgen deprivation therapy.

darolutamide 300 mg tablet, 112

13769Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3537.77	31.60	Nubeqa [BN]

▪ DESMOPRESSIN

Authority required (STREAMLINED)

15012

Cranial diabetes insipidus

Clinical criteria:

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

desmopressin acetate 200 microgram tablet, 30

13889B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	6	5	..	*217.23	31.60	Minirin [FP]

▪ DESMOPRESSIN

Note Not to be used in preference to enuresis alarms.

Authority required (STREAMLINED)

14945

Primary nocturnal enuresis

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 6 years of age or older.

Clinical criteria:

- Patient must be refractory to an enuresis alarm.

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

Authority required (STREAMLINED)

15025

Primary nocturnal enuresis

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 6 years of age or older.


Clinical criteria:

- Patient must be one in whom an enuresis alarm is contraindicated.

The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

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

desmopressin 240 microgram sublingual wafer, 30

13890C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*140.09	31.60	Minirin Melt [FP]

■ DESMOPRESSIN

Note Not to be used in preference to enuresis alarms.

Authority required (STREAMLINED)

14972

Primary nocturnal enuresis

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 6 years of age or older.

Clinical criteria:

- Patient must be refractory to an enuresis alarm.
- No more than twice the maximum quantity will be authorised.

Authority required (STREAMLINED)

14842

Primary nocturnal enuresis

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 6 years of age or older.


Clinical criteria:

- Patient must be one in whom an enuresis alarm is contraindicated.


The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

No more than twice the maximum quantity will be authorised.

desmopressin acetate 200 microgram tablet, 30

13945Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*79.41	31.60	Minirin [FP]

desmopressin 120 microgram sublingual wafer, 30

14004C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*87.01	31.60	Minirin Melt [FP]

■ DEXAMETHASONE


Note Shared Care Model:

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

Restricted benefit

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

dexamethasone 500 microgram tablet, 30

14007F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	4	..	*18.41	19.81	Dexamethasone [AS]

■ DUTASTERIDE

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)

15018

Benign prostatic hyperplasia

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 lower urinary tract symptoms, **AND**
- Patient must have moderate to severe benign prostatic hyperplasia, **AND**
- The treatment must be in combination with an alpha-antagonist.

dutasteride 500 microgram capsule, 30

13900N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*45.71	31.60	^a APO-Dutasteride [TX]
			^B 14.00	*59.71	31.60	^a Avodart [GK]

▪ DUTASTERIDE + TAMSULOSIN

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)

15004

Benign prostatic hyperplasia

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 lower urinary tract symptoms, **AND**
- Patient must have moderate to severe benign prostatic hyperplasia.

dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram modified release capsule, 30

13929D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*48.79	31.60	^a Doubluts [GC]
			^B 7.00	*55.79	31.60	^a Duodart 500ug/400ug [GK]

▪ EMPAGLIFLOZIN

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

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

Authority required (STREAMLINED)

15047

Chronic heart failure

Clinical criteria:

- Patient must be symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.

empagliflozin 10 mg tablet, 30

12918X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	61.01	31.60	Jardiance [BY]

▪ EMPAGLIFLOZIN

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

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

Authority required (STREAMLINED)

15051

Chronic heart failure

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 be symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug, **AND**
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated, **AND**
- Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.

empagliflozin 10 mg tablet, 30

14018T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*109.03	31.60	Jardiance [BY]

■ EMPAGLIFLOZIN

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)

14905

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; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, 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 despite treatment with either metformin or a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with a gliptin and an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1.

Authority required (STREAMLINED)

14974

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 insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, 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 prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1.

Authority required (STREAMLINED)

14949

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, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, 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 prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1.

Note PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

Authority required (STREAMLINED)

14859

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

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, **AND**
- The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1 analogue.


Note PBS-subsidised dual oral therapy does not include combination use of: a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

empagliflozin 10 mg tablet, 30

13845Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*109.03	31.60	Jardiance [BY]

empagliflozin 25 mg tablet, 30

13920P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*109.03	31.60	Jardiance [BY]

▪ EMPAGLIFLOZIN + LINAGLIPTIN

Note This fixed dose combination is not PBS-subsidised for use as a sole therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, an insulin, another dipeptidyl peptidase 4 inhibitor (gliptin), or another SGLT2 inhibitor.

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)

14885

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

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, **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

empagliflozin 10 mg + linagliptin 5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13904T	2	5	..	*154.05	31.60	Glyxambi [BY]

NP

empagliflozin 25 mg + linagliptin 5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13958P	2	5	..	*154.05	31.60	Glyxambi [BY]

NP

▪ EMPAGLIFLOZIN + 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.

Authority required (STREAMLINED)

14925

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

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 previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and empagliflozin.

Note This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

Authority required (STREAMLINED)

14878

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 a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; **OR**
- Patient must have, or have had, 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 prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

Note This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

Note PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

Authority required (STREAMLINED)

14881

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 insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; **OR**
- Patient must have, or have had, 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 prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

Note This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

Authority required (STREAMLINED)

14924

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

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 a dipeptidyl peptidase 4 inhibitor (gliptin), **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

Note This fixed dose combination is not PBS-subsidised for initiating dual oral combination treatment or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, or another SGLT2 inhibitor.

Note PBS-subsidised dual oral therapy does not include combination use of: a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60

14029J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*112.25	31.60	Jardiamet 5 mg/500 mg [BY]

empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60

13852C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*115.41	31.60	Jardiamet 5 mg/1000 mg [BY]

empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60

13903R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*112.25	31.60	Jardiamet 12.5 mg/500 mg [BY]

empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60

13987E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*115.41	31.60	Jardiamet 12.5 mg/1000 mg [BY]

■ ENZALUTAMIDE

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

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

Note Special Pricing Arrangements apply.

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

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

Authority required

Castration resistant metastatic carcinoma of the prostate

Clinical criteria:

- The treatment must not be used in combination with chemotherapy, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.

enzalutamide 40 mg capsule, 112

10174L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	3478.58	31.60	Xtandi [LL]

▪ **ENZALUTAMIDE**

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

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

Note Special Pricing Arrangements apply.

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

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

Castration resistant non-metastatic carcinoma of the prostate

Clinical criteria:

- The condition must have evidence of an absence of distant metastases on the most recently performed conventional medical imaging used to evaluate the condition, **AND**
- The condition must be associated with a prostate-specific antigen level that was observed to have at least doubled in value in a time period of within 10 months anytime prior to first commencing treatment with this drug, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.

Treatment criteria:

- Patient must be undergoing concurrent treatment with androgen deprivation therapy.

Prescribing instructions:

Retain the results of all investigative imaging and prostate-specific antigen (PSA) level measurements on the patient's medical records - do not submit copies of these with this authority application.

The PSA level doubling time must be based on at least three PSA levels obtained within a time period of 10 months any time prior to first commencing a novel hormonal drug for this condition. The third reading is to demonstrate that the doubling was durable and must be at least 1 week apart from the second reading.

enzalutamide 40 mg capsule, 112

13118K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3478.58	31.60	Xtandi [LL]

▪ **ENZALUTAMIDE**

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

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

Metastatic castration sensitive carcinoma of the prostate

Clinical criteria:

- The treatment must be/have been initiated within 6 months of treatment initiation with androgen deprivation therapy, **AND**
- Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); OR
- Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

Treatment criteria:

- Patient must be undergoing concurrent androgen deprivation therapy.

enzalutamide 40 mg capsule, 112

13353T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3478.58	31.60	Xtandi [LL]

▪ **EPROSARTAN**

Restricted benefit

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

eprosartan 600 mg tablet, 28

13912F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	T5.24	*41.55	31.60	Teveten [GO]



▪ **EPROSARTAN**

Authority required

Adverse effects occurring with all of the base-priced drugs

Clinical criteria:

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

Authority required

Drug interactions occurring with all of the base-priced drugs

Clinical criteria:

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

Authority required

Drug interactions expected to occur with all of the base-priced drugs

Clinical criteria:

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

Authority required

Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance

Clinical criteria:

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

eprosartan 600 mg tablet, 28

13861M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	T5.24	*41.55	31.60	Teveten [GO]



▪ **ESTRADIOL**

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.

estradiol valerate 1 mg tablet, 56

13872D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*19.25	20.65	Progynova [BN]



estradiol valerate 2 mg tablet, 56

13980T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*21.89	23.29	Progynova [BN]



estradiol 2 mg tablet, 56

13931F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*25.39	26.79	Zumenon [GO]



estradiol 10 microgram modified release pessary, 18

13978Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	2	..	*46.11	31.60	^a Estro-Pess [AS]	^a Vagifem Low [NO]

■ ESTRADIOL

Note Estradiol should be used in conjunction with an oral progestogen in women with an intact uterus.


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.

estradiol 0.1% (1 mg/g) gel, 28 x 1 g sachets

14026F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	5	..	*31.55	31.60	Sandrena [OX]


■ ESTRADIOL (&) ESTRADIOL + DYDROGESTERONE**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.

estradiol 2 mg tablet [14] (&) estradiol 2 mg + dydrogesterone 10 mg tablet [14], 28

13930E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	5	..	*34.45	31.60	Femoston 2/10 [GO]

estradiol 1 mg tablet [14] (&) estradiol 1 mg + dydrogesterone 10 mg tablet [14], 28

14024D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	5	..	*34.45	31.60	Femoston 1/10 [GO]


■ ESTRADIOL + NORETHISTERONE ACETATE**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.

estradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch, 8

13902Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	5	..	*53.53	31.60	Estalis continuous 50/140 [SZ]


■ ESTRIOLO**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.

estriol 500 microgram pessary, 15

14059Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	2	..	*38.61	31.60	Ovestin Ovula [AS]

estriol 0.1% (1 mg/g) cream, 15 g

13926Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	1	..	*35.63	31.60	Ovestin [AS]

■ ETHOSUXIMIDE**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.

ethosuximide 250 mg/5 mL oral liquid, 200 mL

14014N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	5	..	*135.23	31.60	Zarontin [IX]

▪ **EVEROLIMUS**

Caution Careful monitoring of patients is mandatory.

Restricted benefit

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

everolimus 750 microgram tablet, 60

14040Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	3	..	*1735.65	31.60	^a Certican [NV]	^a Everocan [CR]

everolimus 1 mg tablet, 60

13941R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	3	..	*2283.85	31.60	^a Certican [NV]	^a Everocan [CR]

▪ **EXEMESTANE**

Restricted benefit

Metastatic (Stage IV) breast cancer

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 hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- Patient must be receiving PBS-subsidised everolimus concomitantly for this condition.

Population criteria:

- Patient must not be pre-menopausal.

exemestane 25 mg tablet, 30

14036R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*103.85	31.60	^a APO-Exemestane [TX] ^a Exemestane Sandoz [SZ]	^a Exemestane GH [GQ]
			^b 6.56	*110.41	31.60	^a Aromasin [PF]	

▪ **EXEMESTANE**

Note This drug is not PBS-subsidised for primary prevention of breast cancer.

Note This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer extended beyond 5 years, i.e. a patient who has received 2 years of tamoxifen therapy may only receive 3 years of PBS-subsidised treatment with exemestane.

Note Shared Care Model:

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


Restricted benefit

Breast cancer

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 hormone receptor positive.

exemestane 25 mg tablet, 30

13857H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*103.85	31.60	^a APO-Exemestane [TX] ^a Exemestane Sandoz [SZ]	^a Exemestane GH [GQ]
			^b 6.56	*110.41	31.60	^a Aromasin [PF]	

▪ **GLIBENCLAMIDE**

Caution Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

Restricted benefit

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

glibenclamide 5 mg tablet, 100

13868X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*20.51	21.91	Daonil [SW]

GLICLAZIDE

Caution Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

Restricted benefit

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

gliclazide 60 mg modified release tablet, 60

13922R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.63	24.03	^a ARDIX GLICLAZIDE 60mg MR [XT]	^a Gliclazide Lupin MR [GQ]
						^a Pharmacor Gliclazide MR [CR]	
			^B 15.40	*38.03	24.03	^a Diamicon 60mg MR [SE]	

gliclazide 80 mg tablet, 100

13896J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*24.71	26.11	^a APO-Gliclazide [TX]	^a APX-Gliclazide [TY]
						^a Glyade [AF]	^a Nidem [RW]

GLIMEPIRIDE

Caution Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

Restricted benefit

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

glimepiride 1 mg tablet, 30

13848W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.41	19.81	^a Aylide 1 [AF]	^a Glimepiride APOTEX [GX]
						^a Glimepiride Sandoz [SZ]	
			^B 4.42	*22.83	19.81	^a Amaryl [SW]	

glimepiride 2 mg tablet, 30

13870B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.41	19.81	^a Aylide 2 [AF]	^a Glimepiride APOTEX [GX]
						^a Glimepiride Sandoz [SZ]	

glimepiride 3 mg tablet, 30

14020X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.79	20.19	^a Aylide 3 [AF]	^a Glimepiride APOTEX [GX]
						^a Glimepiride Sandoz [SZ]	

glimepiride 4 mg tablet, 30

14055R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*19.87	21.27	^a Aylide 4 [AF]	^a Glimepiride APOTEX [GX]
						^a Glimepiride Sandoz [SZ]	

GLIPIZIDE

Caution Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

Restricted benefit

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

glipizide 5 mg tablet, 100

14019W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*29.13	30.53	^a Melizide [AF]	^a Minidiab [PF]

HYDROCORTISONE**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.

hydrocortisone 4 mg tablet, 50

13863P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	4	..	*41.91	31.60	^a Hydrocortisone Viatris 4 [AL]
			^B 6.00	*47.91	31.60	^a Hysone 4 [AF]

■ HYDROMORPHONE

Caution The risk of drug dependence is high.

Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.


Restricted benefit

Severe pain

Clinical criteria:

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

hydromorphone hydrochloride 1 mg/mL oral liquid, 500 mL

14080C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	434.76	31.60	pms-HYDROmorphone [DZ]

■ HYDROMORPHONE

Caution The risk of drug dependence is high.

Note Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

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

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

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

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

Restricted benefit

Severe pain

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

Clinical criteria:

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

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

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

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

Restricted benefit

Severe pain

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

Clinical criteria:

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

Authorities for increased maximum quantities and/or repeats must only be considered for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

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

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

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

Restricted benefit

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

Clinical criteria:

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

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

(i) severe disabling pain associated with malignant neoplasia; or

(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or

(iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or


(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

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

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

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

hydromorphone hydrochloride 1 mg/mL oral liquid, 500 mL

14076W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	434.76	31.60	pms-HYDRomorphone [DZ]

▪ **IBRUTINIB**

Note The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:

- (1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and
- (2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.

See the following literature reference for details:

Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. **Blood** vol. 131, 25 (2018): 2745-2760.

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

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

Treatment Phase: Treatment of relapsed/refractory disease

Clinical criteria:

- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.

Treatment criteria:

- Patient must not be undergoing retreatment (second/subsequent treatment course) with this drug where prior treatment of CLL/SLL with this same drug was unable to prevent disease progression, **AND**
- Patient must be undergoing treatment through this treatment phase listing for the first time (initial treatment); OR
- Patient must be undergoing continuing treatment through this treatment phase listing, with disease progression being absent.

ibrutinib 280 mg tablet, 30

14074R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5356.50	31.60	Imbruvica [JC]

ibrutinib 420 mg tablet, 30

14085H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	7953.68	31.60	Imbruvica [JC]

■ IBRUTINIB

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 For the purposes of administering this restriction, current Bruton's tyrosine kinase inhibitors are: acalabrutinib, ibrutinib, zanubrutinib

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

Mantle cell lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must be untreated with Bruton's tyrosine kinase inhibitor therapy; OR
- Patient must have developed intolerance to another Bruton's tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal, when treated for this PBS indication.

Authority required

Mantle cell lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition.

ibrutinib 280 mg tablet, 30

14079B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5356.50	31.60	Imbruvica [JC]

ibrutinib 420 mg tablet, 30

14075T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	7953.68	31.60	Imbruvica [JC]

ibrutinib 560 mg tablet, 30

14086J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	10550.86	31.60	Imbruvica [JC]

ibrutinib 140 mg capsule, 120


11419B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	10550.86	31.60	Imbruvica [JC]

■ LABETALOL

Restricted benefit

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

labetalol hydrochloride 100 mg tablet, 100

13887X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*39.49	31.60	Presolol 100 [AF]

■ LACOSAMIDE

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)

14857

Intractable partial epileptic seizures

Treatment Phase: Continuing treatment

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

lacosamide 100 mg tablet, 56

13867W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*189.81	31.60	^a Lacoress [LR]	^a Lacosam [AF]

NP

^a Lacosamide ARX [XT]
^a Lacosamide Sandoz [SZ]
^a Vimpat [UC]

^a Lacosamide Lupin [GQ]
^a Vimcosa [CR]

lacosamide 50 mg tablet, 14

14011K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	8	5	..	*99.57	31.60	^a Lacosam [AF] ^a Lacosamide Lupin [GQ] ^a Vimcosa [CR]	^a Lacosamide ARX [XT] ^a Lacosamide Sandoz [SZ] ^a Vimpat [UC]

NP

■ LACOSAMIDE

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

Authority required (STREAMLINED)

14857

Intractable partial epileptic seizures

Treatment Phase: Continuing treatment

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

lacosamide 10 mg/mL oral liquid, 200 mL

14048J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡12	5	..	*708.57	31.60	Vimpat [UC]

NP

lacosamide 150 mg tablet, 56

14053P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*280.57	31.60	^a Lacoress [LR] ^a Lacosamide ARX [XT] ^a Lacosamide Sandoz [SZ] ^a Vimpat [UC]	^a Lacosam [AF] ^a Lacosamide Lupin [GQ] ^a Vimcosa [CR]

NP

lacosamide 200 mg tablet, 56

13951G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*371.47	31.60	^a Lacoress [LR] ^a Lacosamide ARX [XT] ^a Lacosamide Sandoz [SZ] ^a Vimpat [UC]	^a Lacosam [AF] ^a Lacosamide Lupin [GQ] ^a Vimcosa [CR]

NP

■ LACOSAMIDE

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

Note Requests for increases in the maximum quantity (packs) up to 3 times that stated may be authorised.

Authority required (STREAMLINED)

14853

Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures

Clinical criteria:

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

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by a paediatrician, **AND**
- Must be treated by an eligible practitioner type who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Clinical criteria:

- The condition must have failed to be controlled satisfactorily by at least two anti-epileptic drugs prior to when the drug is/was first commenced, **AND**
- The treatment must have been in combination with at least one PBS-subsidised anti-epileptic drug at the time the drug was first commenced.

lacosamide 10 mg/mL oral liquid, 200 mL

14013M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡4	5	..	*241.53	31.60	Vimpat [UC]

NP

■ LACOSAMIDE

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

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

Note For dose titration involving the 100 mg or 150 mg strength, refer to the dose titration listing for these strengths with pack sizes of 14 units. Avoid prescribing a 'broken' quantity under this listing.

Authority required (STREAMLINED)

14853

Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures

Clinical criteria:

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

Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by a paediatrician, **AND**
- Must be treated by an eligible practitioner type who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Clinical criteria:

- The condition must have failed to be controlled satisfactorily by at least two anti-epileptic drugs prior to when the drug is/was first commenced, **AND**
- The treatment must have been in combination with at least one PBS-subsidised anti-epileptic drug at the time the drug was first commenced.

lacosamide 100 mg tablet, 56

13839J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*189.81	31.60	^a Lacosam [AF] ^a Lacosamide Lupin [GQ] ^a Vimcosa [CR]	^a Lacosamide ARX [XT] ^a Lacosamide Sandoz [SZ] ^a Vimpat [UC]

lacosamide 150 mg tablet, 56

13838H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*280.57	31.60	^a Lacosam [AF] ^a Lacosamide Lupin [GQ] ^a Vimcosa [CR]	^a Lacosamide ARX [XT] ^a Lacosamide Sandoz [SZ] ^a Vimpat [UC]

lacosamide 200 mg tablet, 56

13949E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*371.47	31.60	^a Lacosam [AF] ^a Lacosamide Lupin [GQ] ^a Vimcosa [CR]	^a Lacosamide ARX [XT] ^a Lacosamide Sandoz [SZ] ^a Vimpat [UC]

lacosamide 50 mg tablet, 14

14049K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	8	5	..	*99.57	31.60	^a Lacosam [AF] ^a Lacosamide Lupin [GQ] ^a Vimcosa [CR]	^a Lacosamide ARX [XT] ^a Lacosamide Sandoz [SZ] ^a Vimpat [UC]

■ LAMOTRIGINE

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)

14855

Epileptic seizures

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 have failed to be controlled satisfactorily by other anti-epileptic drugs; OR
- Patient must be a woman of childbearing potential.

lamotrigine 100 mg tablet, 56

14052N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*38.35	31.60	^a APX-Lamotrigine [TY] ^a Lamotrigine GH [GQ] ^a NOUMED LAMOTRIGINE [VO] ^a Sandoz Lamotrigine [HX]	^a LAMITAN [RF] ^a Logem [AL] ^a Reedos 100 [ZS]

			^B 8.90	*47.25	31.60	^a Lamictal [AS]	
lamotrigine 200 mg tablet, 56							
13843N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*55.61	31.60	^a APX-Lamotrigine [TY] ^a Lamotrigine GH [GQ] ^a NOUMED LAMOTRIGINE [VO] ^a Sandoz Lamotrigine [HX]	^a LAMITAN [RF] ^a Logem [AL] ^a Reedos 200 [ZS]
			^B 8.90	*64.51	31.60	^a Lamictal [AS]	
lamotrigine 25 mg tablet, 56							
13842M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.13	23.53	^a APX-Lamotrigine [TY] ^a Lamotrigine GH [GQ] ^a NOUMED LAMOTRIGINE [VO] ^a Sandoz Lamotrigine [HX]	^a LAMITAN [RF] ^a Logem [AL] ^a Reedos 25 [ZS]
			^B 9.10	*31.23	23.53	^a Lamictal [AS]	
lamotrigine 5 mg tablet, 56							
14047H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	2	5	..	*25.63	27.03	Lamictal [AS]	
lamotrigine 50 mg tablet, 56							
13975M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*28.21	29.61	^a APX-Lamotrigine [TY] ^a Lamotrigine GH [GQ] ^a NOUMED LAMOTRIGINE [VO] ^a Sandoz Lamotrigine [HX]	^a LAMITAN [RF] ^a Logem [AL] ^a Reedos 50 [ZS]
			^B 8.90	*37.11	29.61	^a Lamictal [AS]	

■ LANTHANUM

Note Shared Care Model:

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

Authority required (STREAMLINED)

14872

Hyperphosphataemia

Treatment Phase: Maintenance following initiation and stabilisation

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 not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

Treatment criteria:

- Patient must be undergoing dialysis for chronic kidney disease.

lanthanum 500 mg chewable tablet, 2 x 45

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14060B	2	5	..	*513.33	31.60	Fosrenol [TK]
NP						

lanthanum 750 mg chewable tablet, 6 x 15

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13986D	2	5	..	*771.11	31.60	Fosrenol [TK]
NP						

lanthanum 1 g chewable tablet, 6 x 15

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13874F	2	5	..	*863.85	31.60	Fosrenol [TK]
NP						

■ LEFLUNOMIDE

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

Restricted benefit

Severe active rheumatoid arthritis

Clinical criteria:

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

leflunomide 10 mg tablet, 30

13940Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*45.89	31.60	^a Arabloc [AV] ^a Ataris 10 [AF] ^a Leflunomide generichealth [HQ] ^a Lunava 10 [RW]	^a Arava [SW] ^a Leflunomide APOTEX [GX] ^a Leflunomide Sandoz [SZ]

leflunomide 20 mg tablet, 30

14069L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*63.09	31.60	^a Arava [SW] ^a Leflunomide APOTEX [GX] ^a Leflunomide Sandoz [SZ]	^a Ataris 20 [AF] ^a Leflunomide generichealth [HQ] ^a Lunava 20 [RW]

▪ LEFLUNOMIDE

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

Restricted benefit

Severe active psoriatic arthritis

Clinical criteria:

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

leflunomide 10 mg tablet, 30

14068K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*45.89	31.60	^a Arabloc [AV] ^a Ataris 10 [AF] ^a Leflunomide generichealth [HQ]	^a Arava [SW] ^a Leflunomide APOTEX [GX] ^a Leflunomide Sandoz [SZ]

leflunomide 20 mg tablet, 30

13998R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*63.09	31.60	^a Arava [SW] ^a Leflunomide APOTEX [GX] ^a Leflunomide Sandoz [SZ]	^a Ataris 20 [AF] ^a Leflunomide generichealth [HQ]

▪ LETROZOLE

Note This drug is not PBS-subsidised for primary prevention of breast cancer.

Note This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer where the total duration of this drug (or any other aromatase inhibitor) treatment extends beyond 5 years.

Note Shared Care Model:

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


Restricted benefit

Breast cancer

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 hormone receptor positive.

letrozole 2.5 mg tablet, 30

13939P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*42.83	31.60	^a Femolet [AF] ^a Letrozole APOTEX [GX]	^a Gynotril [ZS] ^a Letrozole GH [HQ]

			^a Letrozole Sandoz [SZ]	^a Pharmacor Letrozole 2.5 [CR]
^b 7.54	*50.37	31.60	^a Femara 2.5 mg [NV]	

■ LEVETIRACETAM

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)

14964

Partial epileptic seizures

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 have failed to be controlled satisfactorily by other anti-epileptic drugs; OR
- Patient must be a woman of childbearing potential, **AND**
- The treatment must not be given concomitantly with brivaracetam, except for cross titration.

levetiracetam 1 g tablet, 60

13937M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*66.43	31.60	^a APO-Levetiracetam [TX] ^a Kevtam 1000 [AF] ^a Levetiracetam GH [GQ] ^a Levetiracetam SZ [SZ] ^a NOUMED LEVETIRACETAM [VO]	^a Keppra [UC] ^a Levactam [ZS] ^a Levetiracetam Mylan [AL] ^a Levi 1000 [RW]

levetiracetam 250 mg tablet, 60

13992K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*32.23	31.60	^a APO-Levetiracetam [TX] ^a Kevtam 250 [AF] ^a Levetiracetam GH [GQ] ^a Levetiracetam SZ [SZ] ^a NOUMED LEVETIRACETAM [VO]	^a Keppra [UC] ^a Levactam [ZS] ^a Levetiracetam Mylan [AL] ^a Levi 250 [RW]

levetiracetam 500 mg tablet, 60

14034P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*45.05	31.60	^a APO-Levetiracetam [TX] ^a Kevtam 500 [AF] ^a Levetiracetam GH [GQ] ^a Levetiracetam SZ [SZ] ^a NOUMED LEVETIRACETAM [VO]	^a Keppra [UC] ^a Levactam [ZS] ^a Levetiracetam Mylan [AL] ^a Levi 500 [RW]

■ LEVETIRACETAM

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)

14988

Partial epileptic seizures

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 have failed to be controlled satisfactorily by other anti-epileptic drugs; OR
- Patient must be a woman of childbearing potential, **AND**
- Patient must be unable to take a solid dose form of levetiracetam, **AND**
- The treatment must not be given concomitantly with brivaracetam, except for cross titration.

levetiracetam 100 mg/mL oral liquid, 300 mL

13993L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±2	5	..	*138.95	31.60	^a APO-Levetiracetam [TX] ^a Kerron [ZS] ^a Levetiracetam GH [GQ]	^a Keppra [UC] ^a Levetiracetam-AFT [AE]

■ LINAGLIPTIN

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)

14858

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; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, 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 despite treatment with either metformin or a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1.

Authority required (STREAMLINED)

14911

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, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, 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 prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1.

Note PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

Authority required (STREAMLINED)

14950

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 insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2)

inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated;
OR

- Patient must have, or have had, 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 prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1.

Authority required (STREAMLINED)

14954

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

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, **AND**
- The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1 analogue.

Note PBS-subsidised dual oral therapy does not include combination use of: a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

linagliptin 5 mg tablet, 30

13954K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*105.17	31.60	Trajenta [BY]

▪ **LINAGLIPTIN + 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.

Authority required (STREAMLINED)

14935

Diabetes mellitus type 2

Treatment Phase: Continuing

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 previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and linagliptin.

Note This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

Authority required (STREAMLINED)

14888

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 a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR

- Patient must have, or have had, 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 prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

Note This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

Note PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

Authority required (STREAMLINED)

14894

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 insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; **OR**
- Patient must have, or have had, 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 prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

Note This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

Authority required (STREAMLINED)

14891

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

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 a sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

Note This fixed dose combination is not PBS-subsidised for initiating dual oral combination treatment or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, or another dipeptidyl peptidase 4 inhibitor (gliptin).

Note PBS-subsidised dual oral therapy does not include combination use of: a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60

13959Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*113.29	31.60	Trajentamet [BY]

linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60

14065G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*115.53	31.60	Trajentamet [BY]

linagliptin 2.5 mg + metformin hydrochloride 1 g tablet, 60

13879L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*116.45	31.60	Trajentamet [BY]

▪ LIOTHYRONINE**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)**14843**

Thyroid cancer

Clinical criteria:

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

Authority required (STREAMLINED)**14844**

Hypothyroidism

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 for replacement therapy, **AND**
- Patient must have documented intolerance to levothyroxine sodium; OR
- Patient must have documented resistance to levothyroxine sodium.

Authority required (STREAMLINED)**15038**

Hypothyroidism

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 severe hypothyroidism, **AND**
- The treatment must be for initiation of therapy only.

liothyronine sodium 20 microgram tablet, 100

13966C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*101.57	31.60	Tertroxin [AS]

▪ MEDROXYPROGESTERONE**Restricted benefit**

Endometriosis

Clinical criteria:

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

medroxyprogesterone acetate 10 mg tablet, 100

13928C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*58.79	31.60	^a Ralovera [FZ]
			^B 13.40	*72.19	31.60	^a Provera [PF]

▪ MEDROXYPROGESTERONE**Restricted benefit**

Advanced breast cancer

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 hormone receptor positive.

medroxyprogesterone acetate 500 mg tablet, 30

14038W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*187.97	31.60	Provera [PF]

▪ MEDROXYPROGESTERONE**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.

medroxyprogesterone acetate 10 mg tablet, 30

13849X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*26.73	28.13	^a Ralovera [FZ]
			^B 13.40	*40.13	28.13	^a Provera [PF]

medroxyprogesterone acetate 5 mg tablet, 56

13956M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*23.95	25.35	^a Ralovera [FZ]
			^B 9.16	*33.11	25.35	^a Provera [PF]

■ **MEDROXYPROGESTERONE**

Restricted benefit

Breast cancer

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 hormone receptor positive.

Restricted benefit

Endometrial cancer

Clinical criteria:

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

medroxyprogesterone acetate 100 mg tablet, 100

14067J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*134.05	31.60	Provera [PF]

medroxyprogesterone acetate 200 mg tablet, 60

13881N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*151.39	31.60	Provera [PF]

medroxyprogesterone acetate 250 mg tablet, 60

13961T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*187.97	31.60	Provera [PF]

■ **METFORMIN**

Restricted benefit

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

metformin hydrochloride 1 g tablet, 90

14056T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.37	23.77	^a APX-Metformin [TY]	^a Blooms The Chemist Metformin 1000 mg [BG]
						^a Diaformin 1000 [AF]	^a Formet 1000 [RW]
						^a Glucobete 1000 [ZS]	^a Metformin GH [HQ]
						^a Metformin Sandoz [SZ]	
			^B 10.66	*33.03	23.77	^a Diabex 1000 [AL]	

metformin hydrochloride 1 g modified release tablet, 60

13847T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*21.61	23.01	^a APO-Metformin XR 1000 [TX]	^a Blooms the Chemist Metformin XR 1000 [IB]
						^a Diaformin XR 1000 [AF]	^a METEX XR [RF]
						^a Pharmacor Metformin XR [CR]	
						^B 10.72	*32.33

metformin hydrochloride 500 mg tablet, 100

13976N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*19.45	20.85	^a APX-Metformin [TY]	^a Blooms The Chemist Metformin 500 mg [BG]
						^a Diaformin [AF]	^a FORMET 500 [RF]
						^a Glucobete 500 [ZS]	^a Metformin GH [HQ]
						^a Metformin Sandoz [SZ]	
			^B 10.94	*30.39	20.85	^a Diabex [AL]	

metformin hydrochloride 500 mg modified release tablet, 120

13899M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*21.61	23.01	^a APO-Metformin XR 500 [TX]	^a Blooms the Chemist Metformin XR 500 [IB]
						^a Metex XR [RW]	^a Pharmacor Metformin XR [CR]
						^B 10.72	[*] 32.33

metformin hydrochloride 850 mg tablet, 60

13952H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*19.45	20.85	^a APX-Metformin [TY]	^a Blooms The Chemist Metformin 850 mg [BG]
						^a Diaformin 850 [AF]	^a FORMET 850 [RF]
						^a Glucobete 850 [ZS]	^a Metformin Sandoz [SZ]
			^B 10.94	[*] 30.39	20.85	^a Diabex 850 [AL]	

■ METHENAMINE HIPPURATE**Restricted benefit**

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

methenamine hippurate 1 g tablet, 100

14005D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*49.59	31.60	^a Hiprex [IL]	^a Uramet [AS]

■ METHOTREXATE**Restricted benefit**

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

methotrexate 50 mg/2 mL injection, 5 x 2 mL vials

13882P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*67.83	31.60	DBL Methotrexate [PF]

■ MINOXIDIL**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

Severe refractory hypertension

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 initiated by a consultant physician.

minoxidil 10 mg tablet, 100

14041B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*74.83	31.60	Loniten [PF]

■ 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)**15050**

SARS-CoV-2 infection

Clinical criteria:

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

Population criteria:

- Patient must be at least 70 years of age.

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

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

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

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

15062

SARS-CoV-2 infection

Clinical criteria:

- The treatment must be for use when nirmatrelvir (&) ritonavir is contraindicated, **AND**
- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- Patient must 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 PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

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

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

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)

15055

SARS-CoV-2 infection

Clinical criteria:

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

Population criteria:

• Patient must be each of: (i) identify as Aboriginal or Torres Strait Islander, (ii) at least 30 years of age, (iii) at high risk. For the purpose of administering this restriction, high risk is defined as the presence of at least one of the following conditions:

1. The patient is in residential aged care
2. The patient has disability with multiple comorbidities and/or frailty
3. Neurological conditions, including stroke and dementia and demyelinating conditions
4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease
5. Heart failure, coronary artery disease, cardiomyopathies
6. Obesity (BMI greater than 30 kg/m²)
7. Diabetes type I or II, requiring medication for glycaemic control
8. Renal impairment (eGFR less than 60mL/min)
9. Cirrhosis
10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above
11. Past COVID-19 infection episode resulting in hospitalisation.

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

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

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

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

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

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

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)

15056

SARS-CoV-2 infection

Clinical criteria:

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

Population criteria:

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

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

1. The patient is in residential aged care,
2. The patient has disability with multiple comorbidities and/or frailty,
3. Neurological conditions, including stroke and dementia and demyelinating conditions,
4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease,
5. Heart failure, coronary artery disease, cardiomyopathies,
6. Obesity (BMI greater than 30 kg/m²),
7. Diabetes type I or II, requiring medication for glycaemic control,
8. Renal impairment (eGFR less than 60mL/min),
9. Cirrhosis, or
10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above.

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

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

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

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

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

This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection. 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	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	1102.24	31.60	Lagevrio [MK]

▪ MORPHINE

Caution The risk of drug dependence is high.

Note Pharmaceutical benefits that have the brand Ordine 10 may be substituted for pharmaceutical benefits that have the brand Morphini HCl Streuli in case of shortage.

Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

Restricted benefit

Severe pain

Clinical criteria:

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

morphine hydrochloride trihydrate 10 mg/mL oral liquid, 20 mL

14077X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	10	*565.75	31.60	^a Morphini HCl Streuli [DZ]

morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL

5239R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	35.15	31.60	^a Ordine 10 [MF]

▪ MORPHINE

Caution The risk of drug dependence is high.

Note Pharmaceutical benefits that have the brand Ordine 10 may be substituted for pharmaceutical benefits that have the brand Morphini HCl Streuli in case of shortage.

Note Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

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

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

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

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

Restricted benefit

Severe pain

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

Clinical criteria:

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

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

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

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

Restricted benefit

Severe pain

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

Clinical criteria:

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

Authorities for increased maximum quantities and/or repeats must only be considered for:

- (i) severe disabling pain associated with proven malignant neoplasia; or
- (ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
- (iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
- (iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

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

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

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

Restricted benefit

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

Clinical criteria:

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

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:


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

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


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

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

morphine hydrochloride trihydrate 10 mg/mL oral liquid, 20 mL

14083F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	*565.75	31.60	^a Morphini HCl Streuli [DZ]

morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL

2124T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	35.15	31.60	^a Ordine 10 [MF]

▪ **MYCOPHENOLATE**

Caution Careful monitoring of patients is mandatory.

Restricted benefit

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

mycophenolate mofetil 500 mg tablet, 50

14000W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*229.77	31.60	^a CellCept [RO] ^a MycoCept [RF] ^a Mycophenolate GH [GQ] ^a Noumed Mycophenolate [VO]	^a Ceptolate [AF] ^a Mycophenolate APOTEX [GX] ^a Mycophenolate Sandoz [SZ] ^a Pharmacor Mycophenolate 500 [CR]

mycophenolate mofetil 1 g/5 mL powder for oral liquid, 165 mL

14071N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	±2	5	..	*#563.15	31.60	^a CellCept [RO]	^a Pharmacor Mycophenolate [CR]

mycophenolate 180 mg enteric tablet, 120

13856G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*201.69	31.60	^a Mycophenolic Acid ARX [XT]	^a Myfortic [NV]

mycophenolate 360 mg enteric tablet, 120

13938N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*395.35	31.60	^a Mycophenolic Acid ARX [XT] ^a Myfortic [NV]	^a MYCOTEX [CR]

■ MYCOPHENOLATE

Caution Careful monitoring of patients is mandatory.

Note For item codes 13884R and 14037T, pharmaceutical benefits that have the form capsule 250 mg 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.

mycophenolate mofetil 250 mg capsule, 50

14037T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	12	5	..	*229.89	31.60	^a Ceptolate [AF]

mycophenolate mofetil 250 mg capsule, 100

13884R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*229.89	31.60	^a APO-Mycophenolate [TX] ^a Mycophenolate Sandoz [SZ]	^a CellCept [RO] ^a Pharmacor Mycophenolate 250 [CR]

■ 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)

13759

SARS-CoV-2 infection

Clinical criteria:

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

Population criteria:

- Patient must be at least 70 years of age.

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

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

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

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

Authority required (STREAMLINED)

13821

SARS-CoV-2 infection

Clinical criteria:

- Patient must have received a positive polymerase chain reaction (PCR) test result; OR
- Patient must have received a positive rapid antigen test (RAT) result, **AND**
- Patient must have at least one sign or symptom attributable to COVID-19, **AND**
- Patient must not require hospitalisation for COVID-19 infection at the time of prescribing, **AND**
- Patient must 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 PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.

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

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

Authority required (STREAMLINED)

13748

SARS-CoV-2 infection

Clinical criteria:

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

Population criteria:

- Patient must be each of: (i) identify as Aboriginal or Torres Strait Islander, (ii) at least 30 years of age, (iii) at high risk. For the purpose of administering this restriction, high risk is defined as the presence of at least one of the following conditions:

1. The patient is in residential aged care

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

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

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

5. Heart failure, coronary artery disease, cardiomyopathies

6. Obesity (BMI greater than 30 kg/m²)

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

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

9. Cirrhosis

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

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

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

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

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

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

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

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

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

Authority required (STREAMLINED)

15049

SARS-CoV-2 infection

Clinical criteria:

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

Population criteria:

- Patient must be both: (i) at least 50 years of age, (ii) at high risk. For the purpose of administering this restriction, high risk is defined as either a past COVID-19 infection episode resulting in hospitalisation, or the presence of at least two of the following conditions:

1. The patient is in residential aged care,
2. The patient has disability with multiple comorbidities and/or frailty,
3. Neurological conditions, including stroke and dementia and demyelinating conditions,
4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease,
5. Heart failure, coronary artery disease, cardiomyopathies,
6. Obesity (BMI greater than 30 kg/m²),
7. Diabetes type I or II, requiring medication for glycaemic control,
8. Renal impairment (eGFR less than 60mL/min),
9. Cirrhosis, or
10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above.

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

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

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

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

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

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

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

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

12996B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	1114.84	31.60	Paxlovid [PF]

▪ **NORETHISTERONE**

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.

norethisterone 5 mg tablet, 30

13873E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*57.41	31.60	Primolut N [BN]

▪ **NORETHISTERONE ACETATE + ESTRADIOL (&) ESTRADIOL**

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.

estradiol 50 microgram/24 hours patch [4] (&) estradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch [4], 8

13932G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*68.35	31.60	Estalis sequi 50/140 [SZ]

estradiol 50 microgram/24 hours patch [4] (&) estradiol 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch [4], 8

13981W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*72.65	31.60	Estalis sequi 50/250 [SZ]

▪ **OLAPARIB**

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

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

Note Special Pricing Arrangements apply.

Authority required

Castration resistant metastatic carcinoma of the prostate

Treatment Phase: Continuing treatment

Clinical criteria:

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

olaparib 100 mg tablet, 56

12921C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*6631.63	31.60	Lynparza [AP]

olaparib 150 mg tablet, 56

12913P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*6631.63	31.60	Lynparza [AP]

▪ **OLAPARIB**

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

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

Note Special Pricing Arrangements apply.

Authority required

Castration resistant metastatic carcinoma of the prostate

Treatment Phase: Initial treatment

Clinical criteria:

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

Treatment criteria:

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

olaparib 100 mg tablet, 56

12932P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*6631.63	31.60	Lynparza [AP]

olaparib 150 mg tablet, 56

12929L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*6631.63	31.60	Lynparza [AP]

▪ **OLMESARTAN + AMLODIPINE**

Restricted benefit

Hypertension

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 not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

olmesartan medoxomil 40 mg + amlodipine 10 mg tablet, 30

13943W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*26.73	28.13	^a OLMEKAR [RW]	^a Olmesartan/Amlodipine 40/10 APOTEX [TX]
						^a Olmesartan/Amlodipine - MYL 40/10 [AF]	^a Olmesartan/Amlodipine Sandoz [SZ]
						^a Pharmacor Olmesartan Amlodipine 40/10 [CR]	
			^b 5.14	*31.87	28.13	^a Sevikar 40/10 [AL]	

olmesartan medoxomil 40 mg + amlodipine 5 mg tablet, 30

13964Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*25.81	27.21	^a OLMEKAR [RW]	^a Olmesartan/Amlodipine 40/5 APOTEX [TX]
						^a Olmesartan/Amlodipine - MYL 40/5 [AF]	^a Olmesartan/Amlodipine Sandoz [SZ]
						^a Pharmacor Olmesartan Amlodipine 40/5 [CR]	
			^b 5.14	*30.95	27.21	^a Sevikar 40/5 [AL]	

■ OLMESARTAN + AMLODIPINE + HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension

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 not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.

olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 25 mg tablet, 30

14002Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*34.53	31.60	^a APO-Olmesartan/Amlodipine/HCTZ 40/10/25 [TX]	^a Olamlo HCT 40/10/25 [AL]
						^a Olmekar HCT 40/10/25 [RF]	^a Sevikar HCT 40/10/25 [AF]

■ OXCARBAZEPINE

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)

14932

Seizures

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 partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

oxcarbazepine 60 mg/mL oral liquid, 250 mL

13936L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*189.53	31.60	Trileptal [NV]

oxcarbazepine 300 mg tablet, 100

14033N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*157.79	31.60	Trileptal [NV]

oxcarbazepine 600 mg tablet, 100

13935K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*258.27	31.60	Trileptal [NV]

■ OXYBUTYNYN

Restricted benefit

Detrusor overactivity

Clinical criteria:

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

oxybutynin hydrochloride 5 mg tablet, 100

13957N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*21.37	22.77	Ditropan [SW]

■ OXYBUTYNIN**Restricted benefit**

Detrusor overactivity

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 be unable to tolerate oral oxybutynin; OR
- Patient must be unable to swallow oral oxybutynin.

oxybutynin 3.9 mg/24 hours patch, 8

13984B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*50.63	31.60	Oxytrol [TT]

■ PERAMPANEL**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)**14852**

Intractable partial epileptic seizures

Treatment Phase: Continuing

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 previously been issued with an authority prescription for this drug.

perampanel 6 mg tablet, 28

14010J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*450.79	31.60	Fycompa [EI]

perampanel 8 mg tablet, 28

13970G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*598.33	31.60	Fycompa [EI]

perampanel 10 mg tablet, 28

13914H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*598.33	31.60	Fycompa [EI]

perampanel 12 mg tablet, 28

13865R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*598.33	31.60	Fycompa [EI]

perampanel 4 mg tablet, 28

13948D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*303.19	31.60	Fycompa [EI]

■ PERAMPANEL

Note No applications for increased maximum quantities will be authorised.

Note Special Pricing Arrangements apply.

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)**14847**

Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures

Treatment Phase: Continuing treatment

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

Population criteria:

- Patient must be aged 12 years or older.

perampanel 6 mg tablet, 28

14046G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*450.79	31.60	Fycompa [EI]

perampanel 8 mg tablet, 28

13915J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*598.33	31.60	Fycompa [EI]

perampanel 10 mg tablet, 28

13971H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*598.33	31.60	Fycompa [EI]

perampanel 12 mg tablet, 28

14012L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*598.33	31.60	Fycompa [EI]

perampanel 4 mg tablet, 28

13864Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*303.19	31.60	Fycompa [EI]

▪ **PHENOXYMETHYLPENICILLIN**

Restricted benefit

Recurrent streptococcal infections (including rheumatic fever)

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 for prophylaxis.

phenoxymethylpenicillin 250 mg capsule, 50

13968E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*21.23	22.63	Cilicaine VK [AF]	LPV [IL]

phenoxymethylpenicillin 250 mg tablet, 25

14044E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*23.77	25.17	Aspecillin VK [AF]

▪ **PHENYTOIN**

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.

phenytoin 30 mg/5 mL oral liquid, 500 mL

13841L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	3	..	*39.23	31.60	Dilantin [UJ]

phenytoin 50 mg chewable tablet, 200

13894G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*117.57	31.60	Dilantin Infatabs [UJ]

phenytoin sodium 100 mg capsule, 200

13972J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*53.63	31.60	Dilantin Sodium [UJ]

phenytoin sodium 30 mg capsule, 200

14015P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*92.13	31.60	Dilantin Sodium [UJ]

■ PHOSPHORUS

Authority required (STREAMLINED)

14874

Hypophosphataemic rickets

Clinical criteria:

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

Authority required (STREAMLINED)

14962

Vitamin D-resistant rickets

Clinical criteria:

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

Authority required (STREAMLINED)

14921

Familial hypophosphataemia

Clinical criteria:

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

Authority required (STREAMLINED)


14922

Hypercalcaemia

Clinical criteria:

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

phosphorus 500 mg effervescent tablet, 100

13850Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*151.57	31.60	PHOSPHATE PHEBRA [FG]

■ PIOGLITAZONE

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a glucagon-like peptide-1 or an SGLT2 inhibitor.

Authority required (STREAMLINED)

15001

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; **OR**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have a contraindication to a combination of metformin and a sulfonylurea; **OR**
- Patient must not have tolerated a combination of metformin and a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with either metformin or a sulfonylurea; **OR**
- Patient must have, or have had, 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 prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

Authority required (STREAMLINED)

15002

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 insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2)

inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated;
OR

- Patient must have, or have had, 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 prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

Authority required (STREAMLINED)

15014

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, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea; OR
- Patient must have, or have had, 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 prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

pioglitazone 15 mg tablet, 28

13898L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*26.27	27.67	^a Acpio 15 [RF]	^a Actaze [RW]
						^a Actos [EW]	^a APOTEX-Pioglitazone [TX]
						^a Vexazone [AF]	

pioglitazone 30 mg tablet, 28

13921Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*33.45	31.60	^a Acpio 30 [RF]	^a Actaze [RW]
						^a Actos [EW]	^a APOTEX-Pioglitazone [TX]
						^a NOUMED PIOGLITAZONE [VO]	^a Pioglitazone Sandoz [SZ]
						^a Vexazone [AF]	

pioglitazone 45 mg tablet, 28

14057W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*39.59	31.60	^a Acpio 45 [RF]	^a Actaze [RW]
						^a Actos [EW]	^a APOTEX-Pioglitazone [TX]
						^a NOUMED PIOGLITAZONE [VO]	^a Pioglitazone Sandoz [SZ]
						^a Vexazone [AF]	

▪ **PIZOTIFEN**

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.

pizotifen 500 microgram tablet, 100

13866T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*36.21	31.60	Sandomigran 0.5 [AE]

▪ PREDNISOLONE**Restricted benefit**

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

prednisolone 1 mg tablet, 100

13888Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	4	..	*19.19	20.59	^a Predsolone [LN]
			^B 2.00	*21.19	20.59	^a Panafcortelone [AS]

prednisolone 5 mg tablet, 60

14045F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	4	..	*20.07	21.47	Panafcortelone [AS]	Solone [IL]

▪ PREDNISOLONE SODIUM PHOSPHATE**Restricted benefit**

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

prednisolone (as sodium phosphate) 5 mg/mL oral liquid, 30 mL

13837G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*25.77	27.17	^a PredMix [LN]
			^B 4.14	*29.91	27.17	^a Redipred [AS]

▪ PREDNISONE**Restricted benefit**

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

prednisone 1 mg tablet, 100

14043D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	4	..	*19.07	20.47	^a Predsone [LN]
			^B 2.00	*21.07	20.47	^a Panafcort [AS]

prednisone 5 mg tablet, 60

13944X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	4	..	*19.89	21.29	Panafcort [AS]	Sone [IL]

▪ PROBENECID**Restricted benefit**

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

probenecid 500 mg tablet, 100

13942T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*138.95	31.60	Pro-Cid [FF]

▪ PROPANTHELINE**Restricted benefit**

Detrusor overactivity

Clinical criteria:

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

proprantheline bromide 15 mg tablet, 100

13927B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*35.05	31.60	Pro-Banthine [RW]


▪ PROPYLTHIOURACIL**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.

propylthiouracil 50 mg tablet, 100

13836F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	2	..	*75.93	31.60	PTU [FF]

■ QUINAGOLIDE**Restricted benefit**

Pathological hyperprolactinaemia

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 be one in whom surgery is not indicated.

Restricted benefit

Pathological hyperprolactinaemia

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 had surgery for this condition with incomplete resolution.

Restricted benefit

Pathological hyperprolactinaemia

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 be one in whom radiotherapy is not indicated.

Restricted benefit

Pathological hyperprolactinaemia

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 had radiotherapy for this condition with incomplete resolution.

quinagolide 75 microgram tablet, 30

13982X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*137.95	31.60	Norprolac [FP]

■ SAXAGLIPTIN**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)**14858**

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; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, 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 despite treatment with either metformin or a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1.

Authority required (STREAMLINED)

14911

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, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, 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 prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1.

Note PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

Authority required (STREAMLINED)**14954**

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

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, **AND**
- The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1 analogue.

Note PBS-subsidised dual oral therapy does not include combination use of: a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

saxagliptin 2.5 mg tablet, 28

13895H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*99.03	31.60	Onglyza [AP]

saxagliptin 5 mg tablet, 28

13923T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*99.03	31.60	Onglyza [AP]

■ SAXAGLIPTIN + DAPAGLIFLOZIN

Note This fixed dose combination is not PBS-subsidised for use as a sole therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, an insulin, another dipeptidyl peptidase 4 inhibitor (gliptin), or another SGLT2 inhibitor.

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)**14885**

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

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, **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

saxagliptin 5 mg + dapagliflozin 10 mg tablet, 28

13855F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*144.33	31.60	Qtern 5/10 [AP]

▪ SAXAGLIPTIN + 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.

Authority required (STREAMLINED)

14937

Diabetes mellitus type 2

Treatment Phase: Continuing

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 previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and saxagliptin.

Note This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

Authority required (STREAMLINED)

14888

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 a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, 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 prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

Note This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

Note PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

Authority required (STREAMLINED)

14891

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

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 a sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

Note This fixed dose combination is not PBS-subsidised for initiating dual oral combination treatment or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, or another dipeptidyl peptidase 4 inhibitor (gliptin).

Note PBS-subsidised dual oral therapy does not include combination use of: a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

saxagliptin 5 mg + metformin hydrochloride 500 mg modified release tablet, 28

14030K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*105.07	31.60	Kombiglyze XR 5/500 [AP]

saxagliptin 5 mg + metformin hydrochloride 1 g modified release tablet, 28

13876H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*106.57	31.60	Kombiglyze XR 5/1000 [AP]

saxagliptin 2.5 mg + metformin hydrochloride 1 g modified release tablet, 56

13880M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*109.39	31.60	Kombiglyze XR 2.5/1000 [AP]

SEVELAMER

Note Shared Care Model:

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

Note Pharmaceutical benefits that have the forms sevelamer hydrochloride 800 mg and sevelamer carbonate 800 mg tablet are equivalent for the purposes of substitution

Authority required (STREAMLINED)

14984

Hyperphosphataemia

Treatment Phase: Maintenance following initiation and stabilisation

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 not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

Treatment criteria:

- Patient must be undergoing dialysis for chronic kidney disease.

sevelamer carbonate 800 mg tablet, 180

14027G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*366.57	31.60	^a Sevelamer Apotex [TX]	^a Sevelamer Lupin [GQ]

sevelamer hydrochloride 800 mg tablet, 180

13934J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*366.57	31.60	^a Renagel [GZ]

SIROLIMUS

Caution Careful monitoring of patients is mandatory.

Restricted benefit

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

sirolimus 1 mg/mL oral liquid, 60 mL

13885T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	3	..	*1035.05	31.60	Rapamune [PF]

sirolimus 500 microgram tablet, 100

13860L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*671.29	31.60	Rapamune [PF]

sirolimus 1 mg tablet, 100

14072P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*1298.63	31.60	Rapamune [PF]

sirolimus 2 mg tablet, 100

13886W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*2512.25	31.60	Rapamune [PF]

▪ SITAGLIPTIN

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)

14858

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; **OR**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; **OR**
- Patient must have, or have had, 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 despite treatment with either metformin or a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1.

Authority required (STREAMLINED)

14911

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, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; **OR**
- Patient must have, or have had, 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 prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1.

Note PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

Authority required (STREAMLINED)

14950

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 insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, 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 prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1.

Authority required (STREAMLINED)

14954

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

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, **AND**
- The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1 analogue.

Note PBS-subsidised dual oral therapy does not include combination use of: a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

sitagliptin 100 mg tablet, 28

13871C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*74.13	31.60	^a Januvia [XW] ^a Sitagliptin Sandoz Pharma [SZ] ^a Sitaglo [CR]	^a Sitagliptin Lupin [GQ] ^a Sitagliptin SUN [RA] ^a Xelevia [XT]

sitagliptin 25 mg tablet, 28

14021Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*74.13	31.60	^a Januvia [XW] ^a Sitagliptin Sandoz Pharma [SZ] ^a Sitaglo [CR]	^a Sitagliptin Lupin [GQ] ^a Sitagliptin SUN [RA] ^a Xelevia [XT]

sitagliptin 50 mg tablet, 28

14058X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*74.13	31.60	^a Januvia [XW] ^a Sitagliptin Sandoz Pharma [SZ] ^a Sitaglo [CR]	^a Sitagliptin Lupin [GQ] ^a Sitagliptin SUN [RA] ^a Xelevia [XT]

■ SITAGLIPTIN + 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.

Authority required (STREAMLINED)

14933

Diabetes mellitus type 2

Treatment Phase: Continuing

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 previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and sitagliptin.

Note This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

Authority required (STREAMLINED)

14888

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 a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, 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 prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

Note This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

Note PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

Authority required (STREAMLINED)

14894

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 insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, 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 prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

Note This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

Authority required (STREAMLINED)

14891

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

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 a sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

Note This fixed dose combination is not PBS-subsidised for initiating dual oral combination treatment or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, or another dipeptidyl peptidase 4 inhibitor (gliptin).

Note PBS-subsidised dual oral therapy does not include combination use of: a gliptin with an SGLT2 inhibitor; or

- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

sitagliptin 50 mg + metformin hydrochloride 1 g modified release tablet, 56

13990H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*78.51	31.60	^a Janumet XR [XW]	^a Sitagliptin/Metformin Sandoz XR [SZ]

sitagliptin 100 mg + metformin hydrochloride 1 g tablet: modified release, 28

14031L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*76.39	31.60	^a Janumet XR [XW]	^a Sitagliptin/Metformin Sandoz XR [SZ]

sitagliptin 50 mg + metformin hydrochloride 1 g tablet, 56

14035Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*78.51	31.60	^a Janumet [XW]	^a SITAGLIPTIN/METFORMIN 50/1000 SUN [RA]
						^a Sitagliptin/Metformin Sandoz [SZ]	^a Velmetia [XT]

sitagliptin 50 mg + metformin hydrochloride 500 mg tablet, 56

13994M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*76.39	31.60	^a Janumet [XW]	^a SITAGLIPTIN/METFORMIN 50/500 SUN [RA]
						^a Sitagliptin/Metformin Sandoz [SZ]	^a Velmetia [XT]

sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56

14064F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*77.89	31.60	^a Janumet [XW]	^a SITAGLIPTIN/METFORMIN 50/850 SUN [RA]
						^a Sitagliptin/Metformin Sandoz [SZ]	^a Velmetia [XT]

■ SPIRONOLACTONE

Caution Serum electrolytes should be checked regularly

Appropriate contraceptive measures should be taken by women of child-bearing age in whom spironolactone therapy has been initiated.

Restricted benefit

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

spironolactone 100 mg tablet, 100

14042C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*42.61	31.60	^a Spironolactone Viatris 100 [AL]
			^B 9.00	*51.61	31.60	^a Spiractin 100 [AF]
			^B 15.00	*57.61	31.60	^a Aldactone [PF]

■ SUCROFERRIC OXYHYDROXIDE

Note Shared Care Model:

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

Authority required (STREAMLINED)

14872

Hyperphosphataemia

Treatment Phase: Maintenance following initiation and stabilisation

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 not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR

- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

Treatment criteria:

- Patient must be undergoing dialysis for chronic kidney disease.

sucroferic oxyhydroxide 2.5 g (iron 500 mg) chewable tablet, 90

13985C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*816.07	31.60	Velphoro [VL]

▪ **SULTHIAME**

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.

sulthiame 200 mg tablet, 200

14016Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*317.71	31.60	Ospolot [FF]

sulthiame 50 mg tablet, 200

13916K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*125.93	31.60	Ospolot [FF]

▪ **TACROLIMUS**

Caution Careful monitoring of patients is mandatory.

Restricted benefit

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

tacrolimus 3 mg modified release capsule, 50

13996P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*751.07	31.60	ADVAGRAF XL [LQ]

tacrolimus 500 microgram capsule, 100

13908B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	3	..	*150.55	31.60	^a Pacrolim [AF] ^a Prograf [LL] ^a Tacrolimus Sandoz [SZ]	^a Pharmacor Tacrolimus 0.5 [CR] ^a Tacrograf [RW]

tacrolimus 500 microgram modified release capsule, 30

13907Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*93.67	31.60	ADVAGRAF XL [LQ]

tacrolimus 1 mg capsule, 100

14070M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	3	..	*293.15	31.60	^a Pacrolim [AF] ^a Prograf [LL] ^a Tacrolimus Sandoz [SZ]	^a Pharmacor Tacrolimus 1 [CR] ^a Tacrograf [RW]

tacrolimus 1 mg modified release capsule, 60

13962W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*179.09	31.60	ADVAGRAF XL [LQ]

tacrolimus 5 mg capsule, 50

13909C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	3	..	*720.53	31.60	^a Pharmacor Tacrolimus 5 [CR] ^a Tacrograf [RW]	^a Prograf [LL] ^a Tacrolimus Sandoz [SZ]

tacrolimus 5 mg modified release capsule, 30

14039X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*852.79	31.60	ADVAGRAF XL [LQ]

tacrolimus 750 microgram capsule, 100

14066H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*341.35	31.60	Tacrolimus Sandoz [SZ]

tacrolimus 2 mg capsule, 100

13995N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*657.83	31.60	Tacrolimus Sandoz [SZ]

■ TAMOXIFEN

Note For item codes 13960R and 13997Q, pharmaceutical benefits that have the form tablet 20 mg (base) are equivalent for the purposes of substitution.

Note Shared Care Model:

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


Restricted benefit

Breast cancer

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 hormone receptor positive.

tamoxifen 20 mg tablet, 30

13960R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	^B 13.88	*53.85	31.60	^a Nolvadex-D [AP]

■ TAMOXIFEN

Note This pharmaceutical benefit is not PBS-subsidised for primary prevention of breast cancer.

Note For item codes 13960R and 13997Q, pharmaceutical benefits that have the form tablet 20 mg (base) are equivalent for the purposes of substitution.

Note Shared Care Model:

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


Restricted benefit

Breast cancer

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 hormone receptor positive.

tamoxifen 20 mg tablet, 60

13997Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*39.95	31.60	^a Genox 20 [AF] ^a Tamosin [OX]	^a GenRx Tamoxifen [GX] ^a Tamoxifen Sandoz [SZ]

■ TAMOXIFEN

Note A moderate risk of developing breast cancer is if the lifetime breast cancer risk is 1.5 to 3 times the population average. A high risk of developing breast cancer is if the lifetime breast cancer risk is more than 3 times the population average.

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

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


Restricted benefit

Reduction of breast cancer risk

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 a moderate or high risk of developing breast cancer, **AND**
- The treatment must not exceed a dose of 20 mg per day, **AND**
- The treatment must not exceed a lifetime maximum of 5 years for this condition.

tamoxifen 20 mg tablet, 30

13906X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*26.47	27.87	^a Genox 20 [AF]
			^B 6.94	*33.41	27.87	^a Nolvadex-D [AP]

■ TERIPARATIDE

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 Up to a maximum of 18 pens will be reimbursed through the PBS.

Authority required (STREAMLINED)

14997

Severe established osteoporosis

Treatment Phase: Continuing treatment

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 previously been issued with an authority prescription for this drug, **AND**
- The treatment must not exceed a lifetime maximum of 18 months therapy.

Treatment criteria:

- Must be treated by a specialist; OR
- Must be treated by a consultant physician.

teriparatide 250 microgram/mL injection, 2.4 mL cartridge

13891D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*345.67	31.60	Terrosa [FX]

▪ **TESTOSTERONE**

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.

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.

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 eugonadal 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.

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.

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.

The name of the specialist must be included in the authority application.

testosterone 2% (23 mg/actuation) gel, 56 actuations

14025E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	5	..	*156.99	31.60	Testavan [IX]

testosterone 1% (50 mg/5 g) gel, 30 x 5 g sachets

13983Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	5	..	*145.55	31.60	Testogel [HB]

testosterone 1% (12.5 mg/actuation) gel, 2 x 60 actuations

13924W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	4	..	*145.55	31.60	Testogel [HB]

▪ **TIAGABINE**

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)

14883

Partial epileptic seizures

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 have failed to be controlled satisfactorily by other anti-epileptic drugs.

tiagabine 10 mg tablet, 50

13947C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*213.33	31.60	Gabitril [TB]

NP

tiagabine 15 mg tablet, 50

13893F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*303.33	31.60	Gabitril [TB]

NP

tiagabine 5 mg tablet, 50

13892E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*110.77	31.60	Gabitril [TB]

NP

▪ **TOBRAMYCIN**

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

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

Authority required (STREAMLINED)

15040

Proven Pseudomonas aeruginosa infection

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 cystic fibrosis, **AND**
- The treatment must be for management.

tobramycin 300 mg/5 mL inhalation solution, 56 x 5 mL ampoules

14006E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	2	..	*940.03	31.60	^a Tobl [GO]	^a TOBRAMYCIN SUN [RA]
						^a Tobramycin WKT [LI]	

■ TOBRAMYCIN

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)

15036

Proven Pseudomonas aeruginosa infection

Treatment Phase: Continuing treatment

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 cystic fibrosis, **AND**
- Patient must have previously been issued with an authority prescription for tobramycin inhalation capsules, **AND**
- Patient must have demonstrated ability to tolerate the dry powder formulation following the initial 4-week treatment period, as agreed by the patient, the patient's family (in the case of paediatric patients) and the treating physician(s).

Population criteria:

- Patient must be 6 years of age or older.

tobramycin 28 mg powder for inhalation, 224 capsules

13965B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*4727.83	31.60	TOBI podhaler [GO]

■ TOPIRAMATE

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)

14931

Seizures

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 partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures; OR
- Patient must have seizures of the Lennox-Gastaut syndrome, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, **AND**
- Patient must be unable to take a solid dose form of topiramate.

topiramate 15 mg capsule, 60

14063E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*35.61	31.60	Topamax Sprinkle [JC]

NP

topiramate 25 mg capsule, 60

13905W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*31.61	31.60	Topamax Sprinkle [JC]

NP

topiramate 50 mg capsule, 60

13878K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*44.05	31.60	Topamax Sprinkle [JC]

NP

■ TOPIRAMATE

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)

14973

Seizures

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 partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures; OR
- Patient must have seizures of the Lennox-Gastaut syndrome, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

topiramate 200 mg tablet, 60

14009H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*58.51	31.60	^a APO-Topiramate [TX] ^a NOUMED TOPIRAMATE [VO] ^a Tamate [AF] ^a Topiramate Sandoz [SZ]	^a Epiramax 200 [RW] ^a RBX Topiramate [RA] ^a Topamax [JC]

■ TOPIRAMATE

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)

14973

Seizures

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 partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures; OR
- Patient must have seizures of the Lennox-Gastaut syndrome, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

Authority required (STREAMLINED)

14901

Migraine

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 for prophylaxis, **AND**
- Patient must have experienced an average of 3 or more migraines per month over a period of at least 6 months, **AND**
- Patient must have a contraindication to beta-blockers, as described in the relevant TGA-approved Product Information; OR
- Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with a beta-blocker, **AND**
- Patient must have a contraindication to pizotifen because the weight gain associated with this drug poses an unacceptable risk; OR
- Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with pizotifen.

Details of the contraindication and/or intolerance(s) must be documented in the patient's medical records when treatment is initiated.

topiramate 100 mg tablet, 60

14008G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*40.09	31.60	^a APO-Topiramate [TX] ^a NOUMED TOPIRAMATE [VO] ^a Tamate [AF] ^a Topiramate Sandoz [SZ]	^a Epiramax 100 [RW] ^a RBX Topiramate [RA] ^a Topamax [JC]

topiramate 25 mg tablet, 60

13969F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*23.49	24.89	^a APO-Topiramate [TX] ^a NOUMED TOPIRAMATE [VO] ^a Tamate [AF] ^a Topiramate Sandoz [SZ]	^a Epiramax 25 [RW] ^a RBX Topiramate [RA] ^a Topamax [JC]

topiramate 50 mg tablet, 60

13913G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*30.21	31.60	^a APO-Topiramate [TX] ^a NOUMED TOPIRAMATE [VO] ^a Tamate [AF] ^a Topiramate Sandoz [SZ]	^a Epiramax 50 [RW] ^a RBX Topiramate [RA] ^a Topamax [JC]

▪ **TOREMIFENE**

Restricted benefit

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

toremifene 60 mg tablet, 30

13859K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*90.31	31.60	Fareston [OX]

▪ **VALPROATE**

Caution There are reports of fatal hepatotoxicity, particularly in children.

There is increasing evidence of dose-related teratogenesis from this drug.

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.

valproate sodium 100 mg tablet, 100

13840K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	2	..	*57.49	31.60	Epilim [SW]

NP

valproate sodium 200 mg enteric tablet, 100

14017R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	2	..	*32.93	31.60	^a Sodium Valproate Sandoz [SZ]	^a Valprease 200 [RW]
						^a Valproate Winthrop EC 200 [WA]	^a Valpro EC 200 [AF]
			^b 3.40	*36.33	31.60	^a Epilim EC [SW]	

NP

valproate sodium 500 mg enteric tablet, 100

13917L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	2	..	*52.45	31.60	^a Sodium Valproate Sandoz [SZ]	^a Valprease 500 [RW]
						^a Valproate Winthrop EC 500 [WA]	^a Valpro EC 500 [AF]
			^b 3.40	*55.85	31.60	^a Epilim EC [SW]	

NP

valproate sodium 200 mg/5 mL oral liquid, 300 mL

13950F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	2	..	*70.65	31.60	Epilim Syrup [SW]

NP

valproate sodium 200 mg/5 mL oral liquid, 300 mL

13973K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	2	..	*70.65	31.60	Epilim Liquid [SW]

NP

▪ **VIGABATRIN**

Caution Visual field defects have been reported with this drug.

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)

14903

Epileptic seizures

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 have failed to be controlled satisfactorily by other anti-epileptic drugs.

vigabatrin 500 mg powder for oral liquid, 60 sachets

13974L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*108.49	31.60	Sabril [SW]

NP

vigabatrin 500 mg tablet, 100

13919N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*162.89	31.60	Sabril [SW]

NP

▪ VILDAGLIPTIN

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

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)

14999

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; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, 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 despite treatment with either metformin or a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

Authority required (STREAMLINED)

14978

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, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, 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 prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

Note PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

Authority required (STREAMLINED)

15000

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 insulin, **AND**

- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, 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 prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

vildagliptin 50 mg tablet, 60

13846R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*100.33	31.60	Galvus [NV]

▪ VILDAGLIPTIN + METFORMIN

Note This fixed dose combination tablet is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor

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)

14887

Diabetes mellitus type 2

Treatment Phase: Continuing

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 previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and vildagliptin.

Authority required (STREAMLINED)

14888

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 a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR
- Patient must have, or have had, 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 prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

Note PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

Authority required (STREAMLINED)

14894

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 insulin, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, 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 prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

vildagliptin 50 mg + metformin hydrochloride 1 g tablet, 60

14032M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*102.21	31.60	Galvumet 50/1000 [NV]

vildagliptin 50 mg + metformin hydrochloride 500 mg tablet, 60

13877J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*99.17	31.60	Galvumet 50/500 [NV]

vildagliptin 50 mg + metformin hydrochloride 850 mg tablet, 60

13991J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*101.33	31.60	Galvumet 50/850 [NV]

■ ZONISAMIDE**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)**14883**

Partial epileptic seizures

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 have failed to be controlled satisfactorily by other anti-epileptic drugs.

zonisamide 100 mg capsule, 56

13854E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*140.57	31.60	Zonegran [GH]

zonisamide 25 mg capsule, 56

13853D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*35.71	31.60	Zonegran [GH]

zonisamide 50 mg capsule, 56

13988F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*50.89	31.60	Zonegran [GH]

Palliative Care

■ HYDROMORPHONE

Caution The risk of drug dependence is high.

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

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

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

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

Authority required (STREAMLINED)

11697

Severe pain

Clinical criteria:

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

Treatment criteria:

- Patient must be undergoing palliative care.

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

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

hydromorphone hydrochloride 1 mg/mL oral liquid, 500 mL

14084G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	434.76	31.60	pms-HYDRomophone [DZ]

■ MORPHINE

Caution The risk of drug dependence is high.

Note Pharmaceutical benefits that have the brand Ordine 10 may be substituted for pharmaceutical benefits that have the brand Morphini HCl Streuli in case of shortage.

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

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

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

Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

Authority required (STREAMLINED)

11697

Severe pain

Clinical criteria:

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

Treatment criteria:

- Patient must be undergoing palliative care.

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

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

morphine hydrochloride trihydrate 10 mg/mL oral liquid, 20 mL

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14081D	20	1	..	*1118.35	31.60	^a Morphini HCl Streuli [DZ]

NP

morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12472K	2	1	..	*52.13	31.60	^a Ordine 10 [MF]

NP

Highly Specialised Drugs Program (Private Hospital)

▪ FILGRASTIM

Note Pharmaceutical benefits that have the forms filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes and filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

8674

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; OR
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

Authority required (STREAMLINED)

8667

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

Authority required (STREAMLINED)

8672

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

Authority required (STREAMLINED)

8668

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

Authority required (STREAMLINED)

8671

Assisting bone marrow transplantation

Clinical criteria:

- Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

Authority required (STREAMLINED)

8696

Assisting autologous peripheral blood progenitor cell transplantation

Clinical criteria:

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

Authority required (STREAMLINED)

8669

Severe congenital neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, **AND**
- Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

Authority required (STREAMLINED)

8670

Severe chronic neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; OR
- Patient must have neutrophil dysfunction, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

Authority required (STREAMLINED)

8673

Chronic cyclical neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes

6292E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*488.27	^a Nivestim [PF]

filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes

2733W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	11	..	*488.25	^a Zarzio [SZ]

▪ **FILGRASTIM**

Note Pharmaceutical benefits that have the forms filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes and filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

8674

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; OR
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

Authority required (STREAMLINED)

8667

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

Authority required (STREAMLINED)

8672

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

Authority required (STREAMLINED)

8668

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

Authority required (STREAMLINED)

8671

Assisting bone marrow transplantation

Clinical criteria:

- Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

Authority required (STREAMLINED)

8696

Assisting autologous peripheral blood progenitor cell transplantation

Clinical criteria:

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

Authority required (STREAMLINED)

8669

Severe congenital neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, **AND**
- Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

Authority required (STREAMLINED)

8670

Severe chronic neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; OR
- Patient must have neutrophil dysfunction, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

Authority required (STREAMLINED)

8673

Chronic cyclical neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes

6291D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*307.77	^a Nivestim [PF]

filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes

2747N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	11	..	*307.77	^a Zarzio [SZ]

▪ **NUSINERSEN**

Note Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos. Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

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

Note Special Pricing Arrangements apply.

Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

Authority required

Pre-symptomatic spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment of pre-symptomatic spinal muscular atrophy (SMA) - Loading doses

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA.

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- The condition must be pre-symptomatic SMA, with genetic confirmation that there are 1 to 2 copies of the survival motor neuron 2 (SMN2) gene; OR
- The condition must be pre-symptomatic SMA, with genetic confirmation that there are 3 copies of the **survival motor neuron 2 (SMN2) gene, AND**

- The condition must be pre-symptomatic, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must not exceed four loading doses (at days 0, 14, 28 and 63) under this restriction, **AND**
- Patient must be untreated with gene therapy.

Population criteria:

- Patient must be aged under 36 months prior to commencing treatment.

Application for authorisation of initial treatment must be in writing (lodged via postal service or electronic upload) and must include:

(a) a completed authority prescription form; and

(b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:

(i) confirmation of genetic diagnosis of SMA; and

(ii) a copy of the results substantiating the number of SMN2 gene copies determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA)

nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial

12176W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	110048.37	Spinraza [BD]

Highly Specialised Drugs Program (Public Hospital)

▪ FILGRASTIM

Note Pharmaceutical benefits that have the forms filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes and filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

7822

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; OR
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

Authority required (STREAMLINED)

7843

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

Authority required (STREAMLINED)

6653

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

Authority required (STREAMLINED)

6654

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

Authority required (STREAMLINED)

6679

Assisting bone marrow transplantation

Clinical criteria:

- Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

Authority required (STREAMLINED)

6655

Assisting autologous peripheral blood progenitor cell transplantation

Clinical criteria:

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

Authority required (STREAMLINED)

6680

Severe congenital neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, **AND**
- Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

Authority required (STREAMLINED)

6621

Severe chronic neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; OR
- Patient must have neutrophil dysfunction, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

Authority required (STREAMLINED)

6640

Chronic cyclical neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes

5742F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*287.88	^a Nivestim [PF]

filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes

2758E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	11	..	*287.88	^a Zarzio [SZ]

▪ **FILGRASTIM**

Note Pharmaceutical benefits that have the forms filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes and filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

7822

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; OR
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

Authority required (STREAMLINED)

7843

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

Authority required (STREAMLINED)

6653

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

Authority required (STREAMLINED)

6654

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

Authority required (STREAMLINED)

6679

Assisting bone marrow transplantation

Clinical criteria:

- Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

Authority required (STREAMLINED)

6655

Assisting autologous peripheral blood progenitor cell transplantation

Clinical criteria:

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

Authority required (STREAMLINED)

6680

Severe congenital neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, **AND**
- Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

Authority required (STREAMLINED)

6621

Severe chronic neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; OR
- Patient must have neutrophil dysfunction, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

Authority required (STREAMLINED)

6640

Chronic cyclical neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes

5744H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*461.44	^a Nivestim [PF]

filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes

2783L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	11	..	*461.44	^a Zarzio [SZ]

▪ **NUSINERSEN**

Note Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos. Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

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

Note Special Pricing Arrangements apply.

Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

Authority required

Pre-symptomatic spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment of pre-symptomatic spinal muscular atrophy (SMA) - Loading doses

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA.

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- The condition must be pre-symptomatic SMA, with genetic confirmation that there are 1 to 2 copies of the survival motor neuron 2 (SMN2) gene; OR
- The condition must be pre-symptomatic SMA, with genetic confirmation that there are 3 copies of the **survival motor neuron 2 (SMN2) gene, AND**

- The condition must be pre-symptomatic, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must not exceed four loading doses (at days 0, 14, 28 and 63) under this restriction, **AND**
- Patient must be untreated with gene therapy.

Population criteria:

- Patient must be aged under 36 months prior to commencing treatment.

Application for authorisation of initial treatment must be in writing (lodged via postal service or electronic upload) and must include:

(a) a completed authority prescription form; and

(b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:

(i) confirmation of genetic diagnosis of SMA; and

(ii) a copy of the results substantiating the number of SMN2 gene copies determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA)

nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial

12177X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	110000.00	Spinraza [BD]