Australian Government

Department of Health and Aged Care

PBS

Schedule of Pharmaceutical Benefits

Summary of Changes

Effective 1 June 2024

Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 June 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 June 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

Additions

Addition – Brand

13801J *Extencilline Benzathine Benzylpenicillin (France), YO* – **BENZATHINE BENZYLPENICILLIN**, benzathine benzylpenicillin 1.2 million units powder for injection [1 vial] (&) inert substance diluent [5 mL vial], 1 pack

12222G *UREMIDE 20, AF* – **FUROSEMIDE**, furosemide 20 mg tablet, 50

Addition – Equivalence Indicator

12222G *Frusemix-M, TY* – **FUROSEMIDE**, furosemide 20 mg tablet, 50

Alterations

Alteration – Note

11755Q **BENZATHINE BENZYLPENICILLIN**, benzathine benzylpenicillin tetrahydrate 1.2 million units (1016.6 mg)/2.3 mL injection, 10 x 2.3 mL syringes *(Bicillin L-A)*

13801J **BENZATHINE BENZYLPENICILLIN**, benzathine benzylpenicillin 1.2 million units powder for injection [1 vial] (&) inert substance diluent [5 mL vial], 1 pack *(Benzylpenicillin Benzathine (Brancaster Pharma, UK), Extencilline Benzathine Benzylpenicillin (France))*

Advance Notices

1 July 2024

Deletion – Brand

13801J *Benzylpenicillin Benzathine (Brancaster Pharma, UK), OJ* – **BENZATHINE BENZYLPENICILLIN**, benzathine benzylpenicillin 1.2 million units powder for injection [1 vial] (&) inert substance diluent [5 mL vial], 1 pack

General Pharmaceutical Benefits

Additions

Addition – Item

14151T **BUDESONIDE + FORMOTEROL**, budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 60 actuations *(Bufomix Easyhaler 200/6)*

14159F **BUDESONIDE + FORMOTEROL**, budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 60 actuations *(Bufomix Easyhaler 200/6)*

14166N **BUDESONIDE + FORMOTEROL**, budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 60 actuations *(Bufomix Easyhaler 200/6)*

14150R **DULAGLUTIDE**, dulaglutide 1.5 mg/0.5 mL injection, 4 x 0.5 mL pen devices *(Trulicity)*

14152W **INCLISIRAN**, inclisiran 284 mg/1.5 mL injection, 1.5 mL syringe *(Leqvio)*

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

14162J **OSIMERTINIB**, osimertinib 40 mg tablet, 30 *(Tagrisso)*

14168Q **OSIMERTINIB**, osimertinib 80 mg tablet, 30 *(Tagrisso)*

14146M **SECUKINUMAB**, secukinumab 150 mg/mL injection, 2 x 1 mL pen devices *(Cosentyx)*

14154Y **SECUKINUMAB**, secukinumab 150 mg/mL injection, 2 x 1 mL pen devices *(Cosentyx)*

14161H **SECUKINUMAB**, secukinumab 150 mg/mL injection, 2 x 1 mL pen devices *(Cosentyx)*

14164L **SECUKINUMAB**, secukinumab 150 mg/mL injection, 2 x 1 mL pen devices *(Cosentyx)*

14149Q **SEMAGLUTIDE**, semaglutide 1.34 mg/mL injection, 1 x 1.5 mL pen device *(Ozempic)*

14163K **SEMAGLUTIDE**, semaglutide 1.34 mg/mL injection, 1 x 3 mL pen device *(Ozempic)*

Addition – Brand

13790T *Extencilline Benzathine Benzylpenicillin (France), YO* – **BENZATHINE BENZYLPENICILLIN**, benzathine benzylpenicillin 1.2 million units powder for injection [1 vial] (&) inert substance diluent [5 mL vial], 1 pack

13816E *Extencilline Benzathine Benzylpenicillin (France), YO* – **BENZATHINE BENZYLPENICILLIN**, benzathine benzylpenicillin 1.2 million units powder for injection [1 vial] (&) inert substance diluent [5 mL vial], 1 pack

13258T *Bufomix Easyhaler 400/12, OX* – **BUDESONIDE + FORMOTEROL**, budesonide 400 microgram/actuation + formoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations

5096F *DICLOXACILLIN VIATRIS 250, MQ* – **DICLOXACILLIN**, dicloxacillin 250 mg capsule, 24

8121K *DICLOXACILLIN VIATRIS 250, MQ* – **DICLOXACILLIN**, dicloxacillin 250 mg capsule, 24

8762E *Estradiol Transdermal System (Sandoz, USA), HX* – **ESTRADIOL**, estradiol 37.5 microgram/24 hours patch, 8

8764G *Estradiol Transdermal System (Sandoz, USA), HX* – **ESTRADIOL**, estradiol 75 microgram/24 hours patch, 8

8765H *Estradiol Transdermal System (Sandoz, USA), HX* – **ESTRADIOL**, estradiol 100 microgram/24 hours patch, 8

13473D *UREMIDE 20, AF* – **FUROSEMIDE**, furosemide 20 mg tablet, 100

13501N *UREMIDE 20, AF* – **FUROSEMIDE**, furosemide 20 mg tablet, 50

1810G *UREMIDE 20, AF* – **FUROSEMIDE**, furosemide 20 mg tablet, 50

2414C *UREMIDE 20, AF* – **FUROSEMIDE**, furosemide 20 mg tablet, 100

1622J *ARX-Methotrexate, XT* – **METHOTREXATE**, methotrexate 2.5 mg tablet, 30

1623K *ARX-Methotrexate, XT* – **METHOTREXATE**, methotrexate 10 mg tablet, 50

2272N *ARX-Methotrexate, XT* – **METHOTREXATE**, methotrexate 10 mg tablet, 15

8187X *APO-OLANZAPINE, TX* – **OLANZAPINE**, olanzapine 10 mg tablet, 28

1594X *Ondansetron Tablets Viatris, AL* – **ONDANSETRON**, ondansetron 4 mg tablet, 10

8224W *Ondansetron Tablets Viatris, AL* – **ONDANSETRON**, ondansetron 4 mg tablet, 4

1595Y *Ondansetron Tablets Viatris, AL* – **ONDANSETRON**, ondansetron 8 mg tablet, 10

5471Y *Ondansetron ODT Viatris, AL* – **ONDANSETRON**, ondansetron 8 mg orally disintegrating tablet, 4

5473C *Ondansetron ODT Viatris, AL* – **ONDANSETRON**, ondansetron 8 mg orally disintegrating tablet, 10

8225X *Ondansetron Tablets Viatris, AL* – **ONDANSETRON**, ondansetron 8 mg tablet, 4

13494F *Perindopril Arginine Sandoz, SZ* – **PERINDOPRIL**, perindopril arginine 2.5 mg tablet, 30

9006B *Perindopril Arginine Sandoz, SZ* – **PERINDOPRIL**, perindopril arginine 2.5 mg tablet, 30

13585B *Perindopril Arginine Sandoz, SZ* – **PERINDOPRIL**, perindopril arginine 5 mg tablet, 30

9007C *Perindopril Arginine Sandoz, SZ* – **PERINDOPRIL**, perindopril arginine 5 mg tablet, 30

13555K *Perindopril Arginine Sandoz, SZ* – **PERINDOPRIL**, perindopril arginine 10 mg tablet, 30

9008D *Perindopril Arginine Sandoz, SZ* – **PERINDOPRIL**, perindopril arginine 10 mg tablet, 30

9202H *Quetiapine Sandoz XR, SZ* – **QUETIAPINE**, quetiapine 50 mg modified release tablet, 60

5458G *Quetiapine Sandoz XR, SZ* – **QUETIAPINE**, quetiapine 150 mg modified release tablet, 60

9203J *Quetiapine Sandoz XR, SZ* – **QUETIAPINE**, quetiapine 200 mg modified release tablet, 60

9204K *Quetiapine Sandoz XR, SZ* – **QUETIAPINE**, quetiapine 300 mg modified release tablet, 60

9205L *Quetiapine Sandoz XR, SZ* – **QUETIAPINE**, quetiapine 400 mg modified release tablet, 60

13466R *Ramipril Viatris, AL* – **RAMIPRIL**, ramipril 2.5 mg tablet, 30

1945J *Ramipril Viatris, AL* – **RAMIPRIL**, ramipril 2.5 mg tablet, 30

13586C *APO-ROSUVASTATIN, TX* – **ROSUVASTATIN**, rosuvastatin 10 mg tablet, 30

2628H *APO-ROSUVASTATIN, TX* – **ROSUVASTATIN**, rosuvastatin 10 mg tablet, 30

8144P *IMIGRAN MIGRAINE, AS* – **SUMATRIPTAN**, sumatriptan 50 mg tablet, 2

10205D *Testosterone ADVZ 1000, BZ* – **TESTOSTERONE UNDECANOATE**, testosterone undecanoate 1 g/4 mL modified release injection, 4 mL vial

Addition – Equivalence Indicator

8762E *Estradot 37.5, SZ* – **ESTRADIOL**, estradiol 37.5 microgram/24 hours patch, 8

8764G *Estradot 75, SZ* – **ESTRADIOL**, estradiol 75 microgram/24 hours patch, 8

8765H *Estradot 100, SZ* – **ESTRADIOL**, estradiol 100 microgram/24 hours patch, 8

10205D *Reandron 1000, BN* – **TESTOSTERONE UNDECANOATE**, testosterone undecanoate 1 g/4 mL modified release injection, 4 mL vial

Addition – Note

13221W **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices *(Adalicip, Yuflyma)*

12330Y **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices *(Amgevita, Hadlima, Hyrimoz, Idacio)*

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

Deletions

Deletion – Brand

13858J *Arimidex, AP* – **ANASTROZOLE**, anastrozole 1 mg tablet, 30

8179L *Arimidex, AP* – **ANASTROZOLE**, anastrozole 1 mg tablet, 30

8315P *Omegapharm Pty Ltd, OE* – **CEFEPIME**, cefepime 1 g injection, 1 vial

8316Q *Omegapharm Pty Ltd, OE* – **CEFEPIME**, cefepime 2 g injection, 1 vial

12114N *Ceftriaxone Alphapharm, AF* – **CEFTRIAXONE**, ceftriaxone 1 g injection, 10 vials

1788D *Ceftriaxone Alphapharm, AF* – **CEFTRIAXONE**, ceftriaxone 1 g injection, 5 vials

1357K *Dosulepin Mylan, AL* – **DOSULEPIN (DOTHIEPIN)**, dosulepin (dothiepin) hydrochloride 25 mg capsule, 50

13369P *Enalapril generichealth, GQ* – **ENALAPRIL**, enalapril maleate 5 mg tablet, 30

1370D *Enalapril generichealth, GQ* – **ENALAPRIL**, enalapril maleate 5 mg tablet, 30

13465Q *Enalapril generichealth, GQ* – **ENALAPRIL**, enalapril maleate 10 mg tablet, 30

1368B *Enalapril generichealth, GQ* – **ENALAPRIL**, enalapril maleate 10 mg tablet, 30

14000W *Noumed Mycophenolate, VO* – **MYCOPHENOLATE**, mycophenolate mofetil 500 mg tablet, 50

8650G *Noumed Mycophenolate, VO* – **MYCOPHENOLATE**, mycophenolate mofetil 500 mg tablet, 50

8370M *ARX-NALTREXONE, XT* – **NALTREXONE**, naltrexone hydrochloride 50 mg tablet, 30

13568D *Nebivolol Viatris, AL* – **NEBIVOLOL**, nebivolol 1.25 mg tablet, 28

9316H *Nebivolol Viatris, AL* – **NEBIVOLOL**, nebivolol 1.25 mg tablet, 28

13441K *Nebivolol Viatris, AL* – **NEBIVOLOL**, nebivolol 10 mg tablet, 28

9312D *Nebivolol Viatris, AL* – **NEBIVOLOL**, nebivolol 10 mg tablet, 28

13921Q *NOUMED PIOGLITAZONE, VO* – **PIOGLITAZONE**, pioglitazone 30 mg tablet, 28

13921Q *Pioglitazone Sandoz, SZ* – **PIOGLITAZONE**, pioglitazone 30 mg tablet, 28

8695P *NOUMED PIOGLITAZONE, VO* – **PIOGLITAZONE**, pioglitazone 30 mg tablet, 28

8695P *Pioglitazone Sandoz, SZ* – **PIOGLITAZONE**, pioglitazone 30 mg tablet, 28

14057W *NOUMED PIOGLITAZONE, VO* – **PIOGLITAZONE**, pioglitazone 45 mg tablet, 28

14057W *Pioglitazone Sandoz, SZ* – **PIOGLITAZONE**, pioglitazone 45 mg tablet, 28

8696Q *NOUMED PIOGLITAZONE, VO* – **PIOGLITAZONE**, pioglitazone 45 mg tablet, 28

8696Q *Pioglitazone Sandoz, SZ* – **PIOGLITAZONE**, pioglitazone 45 mg tablet, 28

13406N *Noumed Rosuvastatin, VO* – **ROSUVASTATIN**, rosuvastatin 5 mg tablet, 30

2606E *Noumed Rosuvastatin, VO* – **ROSUVASTATIN**, rosuvastatin 5 mg tablet, 30

13586C *Noumed Rosuvastatin, VO* – **ROSUVASTATIN**, rosuvastatin 10 mg tablet, 30

2628H *Noumed Rosuvastatin, VO* – **ROSUVASTATIN**, rosuvastatin 10 mg tablet, 30

13588E *Noumed Rosuvastatin, VO* – **ROSUVASTATIN**, rosuvastatin 20 mg tablet, 30

2574L *Noumed Rosuvastatin, VO* – **ROSUVASTATIN**, rosuvastatin 20 mg tablet, 30

13589F *Noumed Rosuvastatin, VO* – **ROSUVASTATIN**, rosuvastatin 40 mg tablet, 30

2594M *Noumed Rosuvastatin, VO* – **ROSUVASTATIN**, rosuvastatin 40 mg tablet, 30

5480K *NOUMED VALACICLOVIR, VO* – **VALACICLOVIR**, valaciclovir 500 mg tablet, 30

8134D *NOUMED VALACICLOVIR, VO* – **VALACICLOVIR**, valaciclovir 500 mg tablet, 30

Deletion – Equivalence Indicator

8315P *Cefepime Kabi, PK* – **CEFEPIME**, cefepime 1 g injection, 1 vial

8316Q *Cefepime Kabi, PK* – **CEFEPIME**, cefepime 2 g injection, 1 vial

8370M *Naltrexone GH, GQ* – **NALTREXONE**, naltrexone hydrochloride 50 mg tablet, 30

Deletion – Note

14101E **INCLISIRAN**, inclisiran 284 mg/1.5 mL injection, 1.5 mL syringe *(Leqvio)*

13252L **LENVATINIB**, lenvatinib 4 mg capsule, 30 *(Lenvima)*

13253M **LENVATINIB**, lenvatinib 10 mg capsule, 30 *(Lenvima)*

13269J **OZANIMOD**, ozanimod 920 microgram capsule, 28 *(Zeposia)*

11416W **PEGINTERFERON ALFA-2A**, peginterferon alfa-2a 135 microgram/0.5 mL injection, 4 x 0.5 mL syringes *(Pegasys)*

11037X **PEGINTERFERON ALFA-2A**, peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes *(Pegasys)*

13898L **PIOGLITAZONE**, pioglitazone 15 mg tablet, 28 *(APOTEX-Pioglitazone, Acpio 15, Actaze, Actos, Vexazone)*

8694N **PIOGLITAZONE**, pioglitazone 15 mg tablet, 28 *(APOTEX-Pioglitazone, Acpio 15, Actaze, Actos, Vexazone)*

13921Q **PIOGLITAZONE**, pioglitazone 30 mg tablet, 28 *(APOTEX-Pioglitazone, Acpio 30, Actaze, Actos, Vexazone)*

8695P **PIOGLITAZONE**, pioglitazone 30 mg tablet, 28 *(APOTEX-Pioglitazone, Acpio 30, Actaze, Actos, Vexazone)*

14057W **PIOGLITAZONE**, pioglitazone 45 mg tablet, 28 *(APOTEX-Pioglitazone, Acpio 45, Actaze, Actos, Vexazone)*

8696Q **PIOGLITAZONE**, pioglitazone 45 mg tablet, 28 *(APOTEX-Pioglitazone, Acpio 45, Actaze, Actos, Vexazone)*

13241X **RUXOLITINIB**, ruxolitinib 5 mg tablet, 56 *(Jakavi)*

13235N **RUXOLITINIB**, ruxolitinib 10 mg tablet, 56 *(Jakavi)*

13250J **UPADACITINIB**, upadacitinib 15 mg modified release tablet, 28 *(Rinvoq)*

13249H **UPADACITINIB**, upadacitinib 30 mg modified release tablet, 28 *(Rinvoq)*

13261Y **USTEKINUMAB**, ustekinumab 90 mg/mL injection, 1 mL syringe *(Stelara)*

13275Q **VOSORITIDE**, vosoritide 400 microgram injection [10 vials] (&) inert substance diluent [10 x 0.5 mL syringes], 1 pack *(Voxzogo)*

13274P **VOSORITIDE**, vosoritide 560 microgram injection [10 vials] (&) inert substance diluent [10 x 0.7 mL syringes], 1 pack *(Voxzogo)*

13270K **VOSORITIDE**, vosoritide 1.2 mg injection [10 vials] (&) inert substance diluent [10 x 0.6 mL syringes], 1 pack *(Voxzogo)*

Deletion – Restriction

13252L **LENVATINIB**, lenvatinib 4 mg capsule, 30 *(Lenvima)*

13253M **LENVATINIB**, lenvatinib 10 mg capsule, 30 *(Lenvima)*

13269J **OZANIMOD**, ozanimod 920 microgram capsule, 28 *(Zeposia)*

13241X **RUXOLITINIB**, ruxolitinib 5 mg tablet, 56 *(Jakavi)*

13235N **RUXOLITINIB**, ruxolitinib 10 mg tablet, 56 *(Jakavi)*

13250J **UPADACITINIB**, upadacitinib 15 mg modified release tablet, 28 *(Rinvoq)*

13249H **UPADACITINIB**, upadacitinib 30 mg modified release tablet, 28 *(Rinvoq)*

13261Y **USTEKINUMAB**, ustekinumab 90 mg/mL injection, 1 mL syringe *(Stelara)*

13275Q **VOSORITIDE**, vosoritide 400 microgram injection [10 vials] (&) inert substance diluent [10 x 0.5 mL syringes], 1 pack *(Voxzogo)*

13274P **VOSORITIDE**, vosoritide 560 microgram injection [10 vials] (&) inert substance diluent [10 x 0.7 mL syringes], 1 pack *(Voxzogo)*

13270K **VOSORITIDE**, vosoritide 1.2 mg injection [10 vials] (&) inert substance diluent [10 x 0.6 mL syringes], 1 pack *(Voxzogo)*

Alterations

Alteration – Authorised Prescriber

		From	*To*
11269D	**EMPAGLIFLOZIN + LINAGLIPTIN**, empagliflozin 10 mg + linagliptin 5 mg tablet, 30 *(Glyxambi)*	M	M,N
11303X	**EMPAGLIFLOZIN + LINAGLIPTIN**, empagliflozin 25 mg + linagliptin 5 mg tablet, 30 *(Glyxambi)*	M	M,N
11286B	**SAXAGLIPTIN + DAPAGLIFLOZIN**, saxagliptin 5 mg + dapagliflozin 10 mg tablet, 28 *(Qtern 5/10)*	M	M,N

Alteration – Note

12414J **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices *(Adalicip, Humira, Yuflyma)*

12454L **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices *(Adalicip, Humira, Yuflyma)*

12356H **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices *(Amgevita, Hadlima, Hyrimoz, Idacio)*

12369B **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices *(Amgevita, Hadlima, Hyrimoz, Idacio)*

12408C **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe *(Humira)*

12448E **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device *(Humira)*

12450G **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device *(Humira)*

12524E **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe *(Humira)*

13897K **ALOGLIPTIN**, alogliptin 6.25 mg tablet, 28 *(Nesina)*

2944Y **ALOGLIPTIN**, alogliptin 6.25 mg tablet, 28 *(Nesina)*

13977P **ALOGLIPTIN**, alogliptin 12.5 mg tablet, 28 *(Nesina)*

2933J **ALOGLIPTIN**, alogliptin 12.5 mg tablet, 28 *(Nesina)*

13953J **ALOGLIPTIN**, alogliptin 25 mg tablet, 28 *(Nesina)*

2986E **ALOGLIPTIN**, alogliptin 25 mg tablet, 28 *(Nesina)*

10035E **ALOGLIPTIN + METFORMIN**, alogliptin 12.5 mg + metformin hydrochloride 1 g tablet, 56 *(Nesina Met 12.5/1000)*

13989G **ALOGLIPTIN + METFORMIN**, alogliptin 12.5 mg + metformin hydrochloride 1 g tablet, 56 *(Nesina Met 12.5/1000)*

10033C **ALOGLIPTIN + METFORMIN**, alogliptin 12.5 mg + metformin hydrochloride 500 mg tablet, 56 *(Nesina Met 12.5/500)*

14062D **ALOGLIPTIN + METFORMIN**, alogliptin 12.5 mg + metformin hydrochloride 500 mg tablet, 56 *(Nesina Met 12.5/500)*

10032B **ALOGLIPTIN + METFORMIN**, alogliptin 12.5 mg + metformin hydrochloride 850 mg tablet, 56 *(Nesina Met 12.5/850)*

14061C **ALOGLIPTIN + METFORMIN**, alogliptin 12.5 mg + metformin hydrochloride 850 mg tablet, 56 *(Nesina Met 12.5/850)*

2267H **BENZATHINE BENZYLPENICILLIN**, benzathine benzylpenicillin tetrahydrate 1.2 million units (1016.6 mg)/2.3 mL injection, 10 x 2.3 mL syringes *(Bicillin L-A)*

5027N **BENZATHINE BENZYLPENICILLIN**, benzathine benzylpenicillin tetrahydrate 1.2 million units (1016.6 mg)/2.3 mL injection, 10 x 2.3 mL syringes *(Bicillin L-A)*

13790T **BENZATHINE BENZYLPENICILLIN**, benzathine benzylpenicillin 1.2 million units powder for injection [1 vial] (&) inert substance diluent [5 mL vial], 1 pack *(Benzylpenicillin Benzathine (Brancaster Pharma, UK), Extencilline Benzathine Benzylpenicillin (France))*

13816E **BENZATHINE BENZYLPENICILLIN**, benzathine benzylpenicillin 1.2 million units powder for injection [1 vial] (&) inert substance diluent [5 mL vial], 1 pack *(Benzylpenicillin Benzathine (Brancaster Pharma, UK), Extencilline Benzathine Benzylpenicillin (France))*

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

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

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

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

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

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

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

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

11364D **DULAGLUTIDE**, dulaglutide 1.5 mg/0.5 mL injection, 4 x 0.5 mL pen devices *(Trulicity)*

10206E **EMPAGLIFLOZIN**, empagliflozin 10 mg tablet, 30 *(Jardiance)*

13845Q **EMPAGLIFLOZIN**, empagliflozin 10 mg tablet, 30 *(Jardiance)*

10202Y **EMPAGLIFLOZIN**, empagliflozin 25 mg tablet, 30 *(Jardiance)*

13920P **EMPAGLIFLOZIN**, empagliflozin 25 mg tablet, 30 *(Jardiance)*

11269D **EMPAGLIFLOZIN + LINAGLIPTIN**, empagliflozin 10 mg + linagliptin 5 mg tablet, 30 *(Glyxambi)*

13904T **EMPAGLIFLOZIN + LINAGLIPTIN**, empagliflozin 10 mg + linagliptin 5 mg tablet, 30 *(Glyxambi)*

11303X **EMPAGLIFLOZIN + LINAGLIPTIN**, empagliflozin 25 mg + linagliptin 5 mg tablet, 30 *(Glyxambi)*

13958P **EMPAGLIFLOZIN + LINAGLIPTIN**, empagliflozin 25 mg + linagliptin 5 mg tablet, 30 *(Glyxambi)*

10627H **EMPAGLIFLOZIN + METFORMIN**, empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60 *(Jardiamet 5 mg/1000 mg)*

13852C **EMPAGLIFLOZIN + METFORMIN**, empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60 *(Jardiamet 5 mg/1000 mg)*

10626G **EMPAGLIFLOZIN + METFORMIN**, empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60 *(Jardiamet 5 mg/500 mg)*

14029J **EMPAGLIFLOZIN + METFORMIN**, empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60 *(Jardiamet 5 mg/500 mg)*

10677Y **EMPAGLIFLOZIN + METFORMIN**, empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60 *(Jardiamet 12.5 mg/1000 mg)*

13987E **EMPAGLIFLOZIN + METFORMIN**, empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60 *(Jardiamet 12.5 mg/1000 mg)*

10633P **EMPAGLIFLOZIN + METFORMIN**, empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60 *(Jardiamet 12.5 mg/500 mg)*

13903R **EMPAGLIFLOZIN + METFORMIN**, empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60 *(Jardiamet 12.5 mg/500 mg)*

14087K **INCLISIRAN**, inclisiran 284 mg/1.5 mL injection, 1.5 mL syringe *(Leqvio)*

13954K **LINAGLIPTIN**, linagliptin 5 mg tablet, 30 *(Trajenta)*

3387G **LINAGLIPTIN**, linagliptin 5 mg tablet, 30 *(Trajenta)*

10038H **LINAGLIPTIN + METFORMIN**, linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60 *(Trajentamet)*

13959Q **LINAGLIPTIN + METFORMIN**, linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60 *(Trajentamet)*

10045Q **LINAGLIPTIN + METFORMIN**, linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60 *(Trajentamet)*

14065G **LINAGLIPTIN + METFORMIN**, linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60 *(Trajentamet)*

10044P **LINAGLIPTIN + METFORMIN**, linagliptin 2.5 mg + metformin hydrochloride 1 g tablet, 60 *(Trajentamet)*

13879L **LINAGLIPTIN + METFORMIN**, linagliptin 2.5 mg + metformin hydrochloride 1 g tablet, 60 *(Trajentamet)*

11620N **OSIMERTINIB**, osimertinib 40 mg tablet, 30 *(Tagrisso)*

12233W **OSIMERTINIB**, osimertinib 40 mg tablet, 30 *(Tagrisso)*

11622Q **OSIMERTINIB**, osimertinib 80 mg tablet, 30 *(Tagrisso)*

12232T **OSIMERTINIB**, osimertinib 80 mg tablet, 30 *(Tagrisso)*

10128C **SAXAGLIPTIN**, saxagliptin 2.5 mg tablet, 28 *(Onglyza)*

13895H **SAXAGLIPTIN**, saxagliptin 2.5 mg tablet, 28 *(Onglyza)*

13923T **SAXAGLIPTIN**, saxagliptin 5 mg tablet, 28 *(Onglyza)*

8983T **SAXAGLIPTIN**, saxagliptin 5 mg tablet, 28 *(Onglyza)*

11286B **SAXAGLIPTIN + DAPAGLIFLOZIN**, saxagliptin 5 mg + dapagliflozin 10 mg tablet, 28 *(Qtern 5/10)*

13855F **SAXAGLIPTIN + DAPAGLIFLOZIN**, saxagliptin 5 mg + dapagliflozin 10 mg tablet, 28 *(Qtern 5/10)*

10048W **SAXAGLIPTIN + METFORMIN**, saxagliptin 2.5 mg + metformin hydrochloride 1 g modified release tablet, 56 *(Kombiglyze XR 2.5/1000)*

13880M **SAXAGLIPTIN + METFORMIN**, saxagliptin 2.5 mg + metformin hydrochloride 1 g modified release tablet, 56 *(Kombiglyze XR 2.5/1000)*

10055F **SAXAGLIPTIN + METFORMIN**, saxagliptin 5 mg + metformin hydrochloride 500 mg modified release tablet, 28 *(Kombiglyze XR 5/500)*

14030K **SAXAGLIPTIN + METFORMIN**, saxagliptin 5 mg + metformin hydrochloride 500 mg modified release tablet, 28 *(Kombiglyze XR 5/500)*

10051B **SAXAGLIPTIN + METFORMIN**, saxagliptin 5 mg + metformin hydrochloride 1 g modified release tablet, 28 *(Kombiglyze XR 5/1000)*

13876H **SAXAGLIPTIN + METFORMIN**, saxagliptin 5 mg + metformin hydrochloride 1 g modified release tablet, 28 *(Kombiglyze XR 5/1000)*

12080T **SEMAGLUTIDE**, semaglutide 1.34 mg/mL injection, 1 x 1.5 mL pen device *(Ozempic)*

12075M **SEMAGLUTIDE**, semaglutide 1.34 mg/mL injection, 1 x 3 mL pen device *(Ozempic)*

14021Y **SITAGLIPTIN**, sitagliptin 25 mg tablet, 28 *(Januvia, Sitagliptin Lupin, Sitagliptin SUN, Sitagliptin Sandoz Pharma, Sitaglo, Xelevia)*

9180E **SITAGLIPTIN**, sitagliptin 25 mg tablet, 28 *(Januvia, Sitagliptin Lupin, Sitagliptin SUN, Sitagliptin Sandoz Pharma, Sitaglo, Xelevia)*

14058X **SITAGLIPTIN**, sitagliptin 50 mg tablet, 28 *(Januvia, Sitagliptin Lupin, Sitagliptin SUN, Sitagliptin Sandoz Pharma, Sitaglo, Xelevia)*

9181F **SITAGLIPTIN**, sitagliptin 50 mg tablet, 28 *(Januvia, Sitagliptin Lupin, Sitagliptin SUN, Sitagliptin Sandoz Pharma, Sitaglo, Xelevia)*

13871C **SITAGLIPTIN**, sitagliptin 100 mg tablet, 28 *(Januvia, Sitagliptin Lupin, Sitagliptin SUN, Sitagliptin Sandoz Pharma, Sitaglo, Xelevia)*

9182G **SITAGLIPTIN**, sitagliptin 100 mg tablet, 28 *(Januvia, Sitagliptin Lupin, Sitagliptin SUN, Sitagliptin Sandoz Pharma, Sitaglo, Xelevia)*

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

9449H **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)*

9450J **SITAGLIPTIN + METFORMIN**, sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56 *(Janumet, SITAGLIPTIN/METFORMIN 50/850 SUN, Sitagliptin/Metformin Sandoz, Velmetia)*

10090C **SITAGLIPTIN + METFORMIN**, sitagliptin 50 mg + metformin hydrochloride 1 g modified release tablet, 56 *(Janumet XR, Sitagliptin/Metformin Sandoz XR)*

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)*

9451K **SITAGLIPTIN + METFORMIN**, sitagliptin 50 mg + metformin hydrochloride 1 g tablet, 56 *(Janumet, SITAGLIPTIN/METFORMIN 50/1000 SUN, Sitagliptin/Metformin Sandoz, Velmetia)*

10089B **SITAGLIPTIN + METFORMIN**, sitagliptin 100 mg + metformin hydrochloride 1 g tablet: modified release, 28 *(Janumet XR, Sitagliptin/Metformin Sandoz XR)*

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

13846R **VILDAGLIPTIN**, vildagliptin 50 mg tablet, 60 *(Galvus)*

3415R **VILDAGLIPTIN**, vildagliptin 50 mg tablet, 60 *(Galvus)*

13877J **VILDAGLIPTIN + METFORMIN**, vildagliptin 50 mg + metformin hydrochloride 500 mg tablet, 60 *(Galvumet 50/500)*

5474D **VILDAGLIPTIN + METFORMIN**, vildagliptin 50 mg + metformin hydrochloride 500 mg tablet, 60 *(Galvumet 50/500)*

13991J **VILDAGLIPTIN + METFORMIN**, vildagliptin 50 mg + metformin hydrochloride 850 mg tablet, 60 *(Galvumet 50/850)*

5475E **VILDAGLIPTIN + METFORMIN**, vildagliptin 50 mg + metformin hydrochloride 850 mg tablet, 60 *(Galvumet 50/850)*

14032M **VILDAGLIPTIN + METFORMIN**, vildagliptin 50 mg + metformin hydrochloride 1 g tablet, 60 *(Galvumet 50/1000)*

5476F **VILDAGLIPTIN + METFORMIN**, vildagliptin 50 mg + metformin hydrochloride 1 g tablet, 60 *(Galvumet 50/1000)*

Alteration – Restriction

12454L **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices *(Adalicip, Humira, Yuflyma)*

12356H **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices *(Amgevita, Hadlima, Hyrimoz, Idacio)*

12450G **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device *(Humira)*

12524E **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe *(Humira)*

13897K **ALOGLIPTIN**, alogliptin 6.25 mg tablet, 28 *(Nesina)*

2944Y **ALOGLIPTIN**, alogliptin 6.25 mg tablet, 28 *(Nesina)*

13977P **ALOGLIPTIN**, alogliptin 12.5 mg tablet, 28 *(Nesina)*

2933J **ALOGLIPTIN**, alogliptin 12.5 mg tablet, 28 *(Nesina)*

13953J **ALOGLIPTIN**, alogliptin 25 mg tablet, 28 *(Nesina)*

2986E **ALOGLIPTIN**, alogliptin 25 mg tablet, 28 *(Nesina)*

10035E **ALOGLIPTIN + METFORMIN**, alogliptin 12.5 mg + metformin hydrochloride 1 g tablet, 56 *(Nesina Met 12.5/1000)*

13989G **ALOGLIPTIN + METFORMIN**, alogliptin 12.5 mg + metformin hydrochloride 1 g tablet, 56 *(Nesina Met 12.5/1000)*

10033C **ALOGLIPTIN + METFORMIN**, alogliptin 12.5 mg + metformin hydrochloride 500 mg tablet, 56 *(Nesina Met 12.5/500)*

14062D **ALOGLIPTIN + METFORMIN**, alogliptin 12.5 mg + metformin hydrochloride 500 mg tablet, 56 *(Nesina Met 12.5/500)*

10032B **ALOGLIPTIN + METFORMIN**, alogliptin 12.5 mg + metformin hydrochloride 850 mg tablet, 56 *(Nesina Met 12.5/850)*

14061C **ALOGLIPTIN + METFORMIN**, alogliptin 12.5 mg + metformin hydrochloride 850 mg tablet, 56 *(Nesina Met 12.5/850)*

12218C **APREMILAST**, apremilast 10 mg tablet [4] (&) apremilast 20 mg tablet [4] (&) apremilast 30 mg tablet [19], 27 *(Otezla)*

12223H **APREMILAST**, apremilast 30 mg tablet, 56 *(Otezla)*

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

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

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

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

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

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

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

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

13649J **DEUCRAVACITINIB**, deucravacitinib 6 mg tablet, 28 *(Sotyktu)*

11364D **DULAGLUTIDE**, dulaglutide 1.5 mg/0.5 mL injection, 4 x 0.5 mL pen devices *(Trulicity)*

10206E **EMPAGLIFLOZIN**, empagliflozin 10 mg tablet, 30 *(Jardiance)*

13845Q **EMPAGLIFLOZIN**, empagliflozin 10 mg tablet, 30 *(Jardiance)*

10202Y **EMPAGLIFLOZIN**, empagliflozin 25 mg tablet, 30 *(Jardiance)*

13920P **EMPAGLIFLOZIN**, empagliflozin 25 mg tablet, 30 *(Jardiance)*

11269D **EMPAGLIFLOZIN + LINAGLIPTIN**, empagliflozin 10 mg + linagliptin 5 mg tablet, 30 *(Glyxambi)*

13904T **EMPAGLIFLOZIN + LINAGLIPTIN**, empagliflozin 10 mg + linagliptin 5 mg tablet, 30 *(Glyxambi)*

11303X **EMPAGLIFLOZIN + LINAGLIPTIN**, empagliflozin 25 mg + linagliptin 5 mg tablet, 30 *(Glyxambi)*

13958P **EMPAGLIFLOZIN + LINAGLIPTIN**, empagliflozin 25 mg + linagliptin 5 mg tablet, 30 *(Glyxambi)*

10627H **EMPAGLIFLOZIN + METFORMIN**, empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60 *(Jardiamet 5 mg/1000 mg)*

13852C **EMPAGLIFLOZIN + METFORMIN**, empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60 *(Jardiamet 5 mg/1000 mg)*

10626G **EMPAGLIFLOZIN + METFORMIN**, empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60 *(Jardiamet 5 mg/500 mg)*

14029J **EMPAGLIFLOZIN + METFORMIN**, empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60 *(Jardiamet 5 mg/500 mg)*

10677Y **EMPAGLIFLOZIN + METFORMIN**, empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60 *(Jardiamet 12.5 mg/1000 mg)*

13987E **EMPAGLIFLOZIN + METFORMIN**, empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60 *(Jardiamet 12.5 mg/1000 mg)*

10633P **EMPAGLIFLOZIN + METFORMIN**, empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60 *(Jardiamet 12.5 mg/500 mg)*

13903R **EMPAGLIFLOZIN + METFORMIN**, empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60 *(Jardiamet 12.5 mg/500 mg)*

14101E **INCLISIRAN**, inclisiran 284 mg/1.5 mL injection, 1.5 mL syringe *(Leqvio)*

13954K **LINAGLIPTIN**, linagliptin 5 mg tablet, 30 *(Trajenta)*

3387G **LINAGLIPTIN**, linagliptin 5 mg tablet, 30 *(Trajenta)*

10038H **LINAGLIPTIN + METFORMIN**, linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60 *(Trajentamet)*

13959Q **LINAGLIPTIN + METFORMIN**, linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60 *(Trajentamet)*

10045Q **LINAGLIPTIN + METFORMIN**, linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60 *(Trajentamet)*

14065G **LINAGLIPTIN + METFORMIN**, linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60 *(Trajentamet)*

10044P **LINAGLIPTIN + METFORMIN**, linagliptin 2.5 mg + metformin hydrochloride 1 g tablet, 60 *(Trajentamet)*

13879L **LINAGLIPTIN + METFORMIN**, linagliptin 2.5 mg + metformin hydrochloride 1 g tablet, 60 *(Trajentamet)*

11620N **OSIMERTINIB**, osimertinib 40 mg tablet, 30 *(Tagrisso)*

12233W **OSIMERTINIB**, osimertinib 40 mg tablet, 30 *(Tagrisso)*

11622Q **OSIMERTINIB**, osimertinib 80 mg tablet, 30 *(Tagrisso)*

12232T **OSIMERTINIB**, osimertinib 80 mg tablet, 30 *(Tagrisso)*

13898L **PIOGLITAZONE**, pioglitazone 15 mg tablet, 28 *(APOTEX-Pioglitazone, Acpio 15, Actaze, Actos, Vexazone)*

8694N **PIOGLITAZONE**, pioglitazone 15 mg tablet, 28 *(APOTEX-Pioglitazone, Acpio 15, Actaze, Actos, Vexazone)*

13921Q **PIOGLITAZONE**, pioglitazone 30 mg tablet, 28 *(APOTEX-Pioglitazone, Acpio 30, Actaze, Actos, Vexazone)*

8695P **PIOGLITAZONE**, pioglitazone 30 mg tablet, 28 *(APOTEX-Pioglitazone, Acpio 30, Actaze, Actos, Vexazone)*

14057W **PIOGLITAZONE**, pioglitazone 45 mg tablet, 28 *(APOTEX-Pioglitazone, Acpio 45, Actaze, Actos, Vexazone)*

8696Q **PIOGLITAZONE**, pioglitazone 45 mg tablet, 28 *(APOTEX-Pioglitazone, Acpio 45, Actaze, Actos, Vexazone)*

10128C **SAXAGLIPTIN**, saxagliptin 2.5 mg tablet, 28 *(Onglyza)*

13895H **SAXAGLIPTIN**, saxagliptin 2.5 mg tablet, 28 *(Onglyza)*

13923T **SAXAGLIPTIN**, saxagliptin 5 mg tablet, 28 *(Onglyza)*

8983T **SAXAGLIPTIN**, saxagliptin 5 mg tablet, 28 *(Onglyza)*

11286B **SAXAGLIPTIN + DAPAGLIFLOZIN**, saxagliptin 5 mg + dapagliflozin 10 mg tablet, 28 *(Qtern 5/10)*

13855F **SAXAGLIPTIN + DAPAGLIFLOZIN**, saxagliptin 5 mg + dapagliflozin 10 mg tablet, 28 *(Qtern 5/10)*

10048W **SAXAGLIPTIN + METFORMIN**, saxagliptin 2.5 mg + metformin hydrochloride 1 g modified release tablet, 56 *(Kombiglyze XR 2.5/1000)*

13880M **SAXAGLIPTIN + METFORMIN**, saxagliptin 2.5 mg + metformin hydrochloride 1 g modified release tablet, 56 *(Kombiglyze XR 2.5/1000)*

10055F **SAXAGLIPTIN + METFORMIN**, saxagliptin 5 mg + metformin hydrochloride 500 mg modified release tablet, 28 *(Kombiglyze XR 5/500)*

14030K **SAXAGLIPTIN + METFORMIN**, saxagliptin 5 mg + metformin hydrochloride 500 mg modified release tablet, 28 *(Kombiglyze XR 5/500)*

10051B **SAXAGLIPTIN + METFORMIN**, saxagliptin 5 mg + metformin hydrochloride 1 g modified release tablet, 28 *(Kombiglyze XR 5/1000)*

13876H **SAXAGLIPTIN + METFORMIN**, saxagliptin 5 mg + metformin hydrochloride 1 g modified release tablet, 28 *(Kombiglyze XR 5/1000)*

12080T **SEMAGLUTIDE**, semaglutide 1.34 mg/mL injection, 1 x 1.5 mL pen device *(Ozempic)*

12075M **SEMAGLUTIDE**, semaglutide 1.34 mg/mL injection, 1 x 3 mL pen device *(Ozempic)*

14021Y **SITAGLIPTIN**, sitagliptin 25 mg tablet, 28 *(Januvia, Sitagliptin Lupin, Sitagliptin SUN, Sitagliptin Sandoz Pharma, Sitaglo, Xelevia)*

9180E **SITAGLIPTIN**, sitagliptin 25 mg tablet, 28 *(Januvia, Sitagliptin Lupin, Sitagliptin SUN, Sitagliptin Sandoz Pharma, Sitaglo, Xelevia)*

14058X **SITAGLIPTIN**, sitagliptin 50 mg tablet, 28 *(Januvia, Sitagliptin Lupin, Sitagliptin SUN, Sitagliptin Sandoz Pharma, Sitaglo, Xelevia)*

9181F **SITAGLIPTIN**, sitagliptin 50 mg tablet, 28 *(Januvia, Sitagliptin Lupin, Sitagliptin SUN, Sitagliptin Sandoz Pharma, Sitaglo, Xelevia)*

13871C **SITAGLIPTIN**, sitagliptin 100 mg tablet, 28 *(Januvia, Sitagliptin Lupin, Sitagliptin SUN, Sitagliptin Sandoz Pharma, Sitaglo, Xelevia)*

9182G **SITAGLIPTIN**, sitagliptin 100 mg tablet, 28 *(Januvia, Sitagliptin Lupin, Sitagliptin SUN, Sitagliptin Sandoz Pharma, Sitaglo, Xelevia)*

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

9449H **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)*

9450J **SITAGLIPTIN + METFORMIN**, sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56 *(Janumet, SITAGLIPTIN/METFORMIN 50/850 SUN, Sitagliptin/Metformin Sandoz, Velmetia)*

10090C	**SITAGLIPTIN + METFORMIN**, sitagliptin 50 mg + metformin hydrochloride 1 g modified release tablet, 56 *(Janumet XR, Sitagliptin/Metformin Sandoz XR)*
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)*
9451K	**SITAGLIPTIN + METFORMIN**, sitagliptin 50 mg + metformin hydrochloride 1 g tablet, 56 *(Janumet, SITAGLIPTIN/METFORMIN 50/1000 SUN, Sitagliptin/Metformin Sandoz, Velmetia)*
10089B	**SITAGLIPTIN + METFORMIN**, sitagliptin 100 mg + metformin hydrochloride 1 g tablet: modified release, 28 *(Janumet XR, Sitagliptin/Metformin Sandoz XR)*
14031L	**SITAGLIPTIN + METFORMIN**, sitagliptin 100 mg + metformin hydrochloride 1 g tablet: modified release, 28 *(Janumet XR, Sitagliptin/Metformin Sandoz XR)*
14100D	**TAFAMIDIS**, tafamidis 61 mg capsule, 30 *(Vyndamax)*
13846R	**VILDAGLIPTIN**, vildagliptin 50 mg tablet, 60 *(Galvus)*
3415R	**VILDAGLIPTIN**, vildagliptin 50 mg tablet, 60 *(Galvus)*
13877J	**VILDAGLIPTIN + METFORMIN**, vildagliptin 50 mg + metformin hydrochloride 500 mg tablet, 60 *(Galvumet 50/500)*
5474D	**VILDAGLIPTIN + METFORMIN**, vildagliptin 50 mg + metformin hydrochloride 500 mg tablet, 60 *(Galvumet 50/500)*
13991J	**VILDAGLIPTIN + METFORMIN**, vildagliptin 50 mg + metformin hydrochloride 850 mg tablet, 60 *(Galvumet 50/850)*
5475E	**VILDAGLIPTIN + METFORMIN**, vildagliptin 50 mg + metformin hydrochloride 850 mg tablet, 60 *(Galvumet 50/850)*
14032M	**VILDAGLIPTIN + METFORMIN**, vildagliptin 50 mg + metformin hydrochloride 1 g tablet, 60 *(Galvumet 50/1000)*
5476F	**VILDAGLIPTIN + METFORMIN**, vildagliptin 50 mg + metformin hydrochloride 1 g tablet, 60 *(Galvumet 50/1000)*

Alteration – Restriction Level

		From	*To*
11364D	**DULAGLUTIDE**, dulaglutide 1.5 mg/0.5 mL injection, 4 x 0.5 mL pen devices *(Trulicity)*	streamlined	authority-required
13898L	**PIOGLITAZONE**, pioglitazone 15 mg tablet, 28 *(APOTEX-Pioglitazone, Acpio 15, Actaze, Actos, Vexazone)*	streamlined	restricted
8694N	**PIOGLITAZONE**, pioglitazone 15 mg tablet, 28 *(APOTEX-Pioglitazone, Acpio 15, Actaze, Actos, Vexazone)*	streamlined	restricted
13921Q	**PIOGLITAZONE**, pioglitazone 30 mg tablet, 28 *(APOTEX-Pioglitazone, Acpio 30, Actaze, Actos, Vexazone)*	streamlined	restricted
8695P	**PIOGLITAZONE**, pioglitazone 30 mg tablet, 28 *(APOTEX-Pioglitazone, Acpio 30, Actaze, Actos, Vexazone)*	streamlined	restricted
14057W	**PIOGLITAZONE**, pioglitazone 45 mg tablet, 28 *(APOTEX-Pioglitazone, Acpio 45, Actaze, Actos, Vexazone)*	streamlined	restricted
8696Q	**PIOGLITAZONE**, pioglitazone 45 mg tablet, 28 *(APOTEX-Pioglitazone, Acpio 45, Actaze, Actos, Vexazone)*	streamlined	restricted
12080T	**SEMAGLUTIDE**, semaglutide 1.34 mg/mL injection, 1 x 1.5 mL pen device *(Ozempic)*	streamlined	authority-required
12075M	**SEMAGLUTIDE**, semaglutide 1.34 mg/mL injection, 1 x 3 mL pen device *(Ozempic)*	streamlined	authority-required

Alteration – Manufacturer Code

		From	*To*
14006E	*Tobramycin WKT* – **TOBRAMYCIN**, tobramycin 300 mg/5 mL inhalation solution, 56 x 5 mL ampoules	LI	JU
5442K	*Tobramycin WKT* – **TOBRAMYCIN**, tobramycin 300 mg/5 mL inhalation solution, 56 x 5 mL ampoules	LI	JU

Alteration – Number of Repeats

		From	*To*

13891D	**TERIPARATIDE**, teriparatide 250 microgram/mL injection, 2.4 mL cartridge *(Terrosa)*	5	2

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 June 2024

1263L	**BISACODYL**, bisacodyl 10 mg/5 mL enema, 25 x 5 mL *(Bisalax)*
11291G	**DAPAGLIFLOZIN**, dapagliflozin 10 mg tablet, 28 *(Forxiga)*
11300R	**DAPAGLIFLOZIN + METFORMIN**, dapagliflozin 5 mg + metformin hydrochloride 1 g modified release tablet, 56 *(Xigduo XR 5/1000)*
11270E	**DAPAGLIFLOZIN + METFORMIN**, dapagliflozin 10 mg + metformin hydrochloride 500 mg modified release tablet, 28 *(Xigduo XR 10/500)*
11313K	**DAPAGLIFLOZIN + METFORMIN**, dapagliflozin 10 mg + metformin hydrochloride 1 g modified release tablet, 28 *(Xigduo XR 10/1000)*
11314L	**EMPAGLIFLOZIN**, empagliflozin 10 mg tablet, 30 *(Jardiance)*
11281R	**EMPAGLIFLOZIN**, empagliflozin 25 mg tablet, 30 *(Jardiance)*
11310G	**EMPAGLIFLOZIN + LINAGLIPTIN**, empagliflozin 10 mg + linagliptin 5 mg tablet, 30 *(Glyxambi)*
11298P	**EMPAGLIFLOZIN + LINAGLIPTIN**, empagliflozin 25 mg + linagliptin 5 mg tablet, 30 *(Glyxambi)*
10649L	**EMPAGLIFLOZIN + METFORMIN**, empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60 *(Jardiamet 5 mg/1000 mg)*
10650M	**EMPAGLIFLOZIN + METFORMIN**, empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60 *(Jardiamet 5 mg/500 mg)*
10640B	**EMPAGLIFLOZIN + METFORMIN**, empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60 *(Jardiamet 12.5 mg/1000 mg)*
10639Y	**EMPAGLIFLOZIN + METFORMIN**, empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60 *(Jardiamet 12.5 mg/500 mg)*
9024Y	**KETOCONAZOLE**, ketoconazole 2% cream, 30 g *(Nizoral 2% Cream)*
11280Q	**LINAGLIPTIN**, linagliptin 5 mg tablet, 30 *(Trajenta)*
11274J	**LINAGLIPTIN + METFORMIN**, linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60 *(Trajentamet)*
11294K	**LINAGLIPTIN + METFORMIN**, linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60 *(Trajentamet)*
11282T	**LINAGLIPTIN + METFORMIN**, linagliptin 2.5 mg + metformin hydrochloride 1 g tablet, 60 *(Trajentamet)*
11292H	**SAXAGLIPTIN**, saxagliptin 2.5 mg tablet, 28 *(Onglyza)*
11311H	**SAXAGLIPTIN**, saxagliptin 5 mg tablet, 28 *(Onglyza)*
11305B	**SAXAGLIPTIN + DAPAGLIFLOZIN**, saxagliptin 5 mg + dapagliflozin 10 mg tablet, 28 *(Qtern 5/10)*
11285Y	**SAXAGLIPTIN + METFORMIN**, saxagliptin 2.5 mg + metformin hydrochloride 1 g modified release tablet, 56 *(Kombiglyze XR 2.5/1000)*
11312J	**SAXAGLIPTIN + METFORMIN**, saxagliptin 5 mg + metformin hydrochloride 500 mg modified release tablet, 28 *(Kombiglyze XR 5/500)*
11299Q	**SAXAGLIPTIN + METFORMIN**, saxagliptin 5 mg + metformin hydrochloride 1 g modified release tablet, 28 *(Kombiglyze XR 5/1000)*
11572C	**SITAGLIPTIN**, sitagliptin 25 mg tablet, 28 *(Januvia, Sitagliptin Lupin, Sitagliptin SUN, Sitagliptin Sandoz Pharma, Sitaglo, Xelevia)*
11573D	**SITAGLIPTIN**, sitagliptin 50 mg tablet, 28 *(Januvia, Sitagliptin Lupin, Sitagliptin SUN, Sitagliptin Sandoz Pharma, Sitaglo, Xelevia)*
11576G	**SITAGLIPTIN**, sitagliptin 100 mg tablet, 28 *(Januvia, Sitagliptin Lupin, Sitagliptin SUN, Sitagliptin Sandoz Pharma, Sitaglo, Xelevia)*
11586T	**SITAGLIPTIN + METFORMIN**, sitagliptin 50 mg + metformin hydrochloride 500 mg tablet, 56 *(Janumet, SITAGLIPTIN/METFORMIN 50/500 SUN, Sitagliptin/Metformin Sandoz, Velmetia)*

11582N **SITAGLIPTIN + METFORMIN**, sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56 *(Janumet, SITAGLIPTIN/METFORMIN 50/850 SUN, Sitagliptin/Metformin Sandoz, Velmetia)*

11574E **SITAGLIPTIN + METFORMIN**, sitagliptin 50 mg + metformin hydrochloride 1 g tablet, 56 *(Janumet, SITAGLIPTIN/METFORMIN 50/1000 SUN, Sitagliptin/Metformin Sandoz, Velmetia)*

11580L **SITAGLIPTIN + METFORMIN**, sitagliptin 50 mg + metformin hydrochloride 1 g modified release tablet, 56 *(Janumet XR, Sitagliptin/Metformin Sandoz XR)*

11566R **SITAGLIPTIN + METFORMIN**, sitagliptin 100 mg + metformin hydrochloride 1 g tablet: modified release, 28 *(Janumet XR, Sitagliptin/Metformin Sandoz XR)*

Advance Notices

1 July 2024

Deletion – Brand

12117R *Calquence, AP* – **ACALABRUTINIB**, acalabrutinib 100 mg capsule, 56

12826C *Calquence, AP* – **ACALABRUTINIB**, acalabrutinib 100 mg capsule, 56

13179P *Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo - Medsurge), DZ* – **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 875 mg + clavulanic acid 125 mg tablet, 20

13190F *Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo - Medsurge), DZ* – **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 875 mg + clavulanic acid 125 mg tablet, 20

13194K *Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo - Medsurge), DZ* – **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 875 mg + clavulanic acid 125 mg tablet, 20

13694R *Amoxicillin and clavulanate potassium for oral suspension, USP 400 mg/57 mg per 5 mL (Aurobindo), DZ* – **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL powder for oral liquid, 50 mL

13728M *Amoxicillin and clavulanate potassium for oral suspension, USP 400 mg/57 mg per 5 mL (Aurobindo), DZ* – **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL powder for oral liquid, 50 mL

8717T *Aripic Aripiprazole, LR* – **ARIPIPRAZOLE**, aripiprazole 10 mg tablet, 30

13468W *Atorvastatin GH, GQ* – **ATORVASTATIN**, atorvastatin 40 mg tablet, 30

13495G *Atorvastatin GH, GQ* – **ATORVASTATIN**, atorvastatin 10 mg tablet, 30

8213G *Atorvastatin GH, GQ* – **ATORVASTATIN**, atorvastatin 10 mg tablet, 30

8215J *Atorvastatin GH, GQ* – **ATORVASTATIN**, atorvastatin 40 mg tablet, 30

13790T *Benzylpenicillin Benzathine (Brancaster Pharma, UK), OJ* – **BENZATHINE BENZYLPENICILLIN**, benzathine benzylpenicillin 1.2 million units powder for injection [1 vial] (&) inert substance diluent [5 mL vial], 1 pack

13816E *Benzylpenicillin Benzathine (Brancaster Pharma, UK), OJ* – **BENZATHINE BENZYLPENICILLIN**, benzathine benzylpenicillin 1.2 million units powder for injection [1 vial] (&) inert substance diluent [5 mL vial], 1 pack

13436E *NOUMED CANDESARTAN, VO* – **CANDESARTAN**, candesartan cilexetil 8 mg tablet, 30

13438G *NOUMED CANDESARTAN, VO* – **CANDESARTAN**, candesartan cilexetil 32 mg tablet, 30

13565Y *NOUMED CANDESARTAN, VO* – **CANDESARTAN**, candesartan cilexetil 16 mg tablet, 30

13592J *NOUMED CANDESARTAN, VO* – **CANDESARTAN**, candesartan cilexetil 4 mg tablet, 30

8295N *NOUMED CANDESARTAN, VO* – **CANDESARTAN**, candesartan cilexetil 4 mg tablet, 30

8296P *NOUMED CANDESARTAN, VO* – **CANDESARTAN**, candesartan cilexetil 8 mg tablet, 30

8297Q *NOUMED CANDESARTAN, VO* – **CANDESARTAN**, candesartan cilexetil 16 mg tablet, 30

8889W *NOUMED CANDESARTAN, VO* – **CANDESARTAN**, candesartan cilexetil 32 mg tablet, 30

11169W *Ceftriaxone Alphapharm, AF* – **CEFTRIAXONE**, ceftriaxone 2 g injection, 5 vials

12112L *Ceftriaxone Alphapharm, AF* – **CEFTRIAXONE**, ceftriaxone 2 g injection, 10 vials

3138E *Clindamycin BNM, BZ* – **CLINDAMYCIN**, clindamycin 150 mg capsule, 24

5057E *Clindamycin BNM, BZ* – **CLINDAMYCIN**, clindamycin 150 mg capsule, 24

3118D *Depo-Ralovera, FZ* – **MEDROXYPROGESTERONE**, medroxyprogesterone acetate 150 mg/mL injection, 1 mL vial

13282C *Penopen, QY* – **PHENOXYMETHYLPENICILLIN**, phenoxymethylpenicillin 250 mg/5 mL powder for oral liquid, 100 mL

13291M *Penopen, QY* – **PHENOXYMETHYLPENICILLIN**, phenoxymethylpenicillin 250 mg/5 mL powder for oral liquid, 100 mL

11993F *Roximycin, AF* – **ROXITHROMYCIN**, roxithromycin 300 mg tablet, 5

12001P *Roximycin, AF* – **ROXITHROMYCIN**, roxithromycin 150 mg tablet, 10

1760P *Roximycin, AF* – **ROXITHROMYCIN**, roxithromycin 150 mg tablet, 10

5260W *Roximycin, AF* – **ROXITHROMYCIN**, roxithromycin 150 mg tablet, 10

5261X *Roximycin, AF* – **ROXITHROMYCIN**, roxithromycin 300 mg tablet, 5

8016X *Roximycin, AF* – **ROXITHROMYCIN**, roxithromycin 300 mg tablet, 5

12670W *Terrosa, FX* – **TERIPARATIDE**, teriparatide 250 microgram/mL injection, 2.4 mL cartridge

13891D *Terrosa, FX* – **TERIPARATIDE**, teriparatide 250 microgram/mL injection, 2.4 mL cartridge

13913G *NOUMED TOPIRAMATE, VO* – **TOPIRAMATE**, topiramate 50 mg tablet, 60

13969F *NOUMED TOPIRAMATE, VO* – **TOPIRAMATE**, topiramate 25 mg tablet, 60

14008G *NOUMED TOPIRAMATE, VO* – **TOPIRAMATE**, topiramate 100 mg tablet, 60

14009H *NOUMED TOPIRAMATE, VO* – **TOPIRAMATE**, topiramate 200 mg tablet, 60

8163P *NOUMED TOPIRAMATE, VO* – **TOPIRAMATE**, topiramate 25 mg tablet, 60

8164Q *NOUMED TOPIRAMATE, VO* – **TOPIRAMATE**, topiramate 50 mg tablet, 60

8165R *NOUMED TOPIRAMATE, VO* – **TOPIRAMATE**, topiramate 100 mg tablet, 60

8166T *NOUMED TOPIRAMATE, VO* – **TOPIRAMATE**, topiramate 200 mg tablet, 60

13341E *APO-Varenicline (Canada), XT* – **VARENICLINE**, varenicline 500 microgram tablet, 56

1 August 2024
Deletion – Brand

8357W *Acamprosate Mylan, AL* – **ACAMPROSATE**, acamprosate calcium 333 mg enteric tablet, 180

13955L *Acarbose Mylan, AF* – **ACARBOSE**, acarbose 50 mg tablet, 90

8188Y *Acarbose Mylan, AF* – **ACARBOSE**, acarbose 50 mg tablet, 90

12115P *Cephazolin Alphapharm, AF* – **CEFAZOLIN**, cefazolin 2 g injection, 10 vials

12118T *Cephazolin Alphapharm, AF* – **CEFAZOLIN**, cefazolin 2 g injection, 10 vials

9159C *Cinacalcet Mylan, AF* – **CINACALCET**, cinacalcet 90 mg tablet, 28

13884R *CellCept, RO* – **MYCOPHENOLATE**, mycophenolate mofetil 250 mg capsule, 100

14000W *CellCept, RO* – **MYCOPHENOLATE**, mycophenolate mofetil 500 mg tablet, 50

8649F *CellCept, RO* – **MYCOPHENOLATE**, mycophenolate mofetil 250 mg capsule, 100

8650G *CellCept, RO* – **MYCOPHENOLATE**, mycophenolate mofetil 500 mg tablet, 50

2335X *Cipla Pregabalin, LR* – **PREGABALIN**, pregabalin 75 mg capsule, 56

2348N *Cipla Pregabalin, LR* – **PREGABALIN**, pregabalin 25 mg capsule, 56

2363J *Cipla Pregabalin, LR* – **PREGABALIN**, pregabalin 300 mg capsule, 56

1 September 2024
Deletion – Brand

11933C *AlphaClav Duo Forte, AF* – **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10

5006L *AlphaClav Duo Forte, AF* – **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10

8254K *AlphaClav Duo Forte, AF* – **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10

Highly Specialised Drugs Program (Private Hospital)

Additions

Addition – Item

14147N **IVACAFTOR**, ivacaftor 25 mg granules, 56 sachets *(Kalydeco)*

14165M **IVACAFTOR**, ivacaftor 25 mg granules, 56 sachets *(Kalydeco)*

14158E **IVACAFTOR**, ivacaftor 50 mg granules, 56 sachets *(Kalydeco)*

14157D **IVACAFTOR**, ivacaftor 75 mg granules, 56 sachets *(Kalydeco)*

14169R **IVACAFTOR**, ivacaftor 150 mg tablet, 56 *(Kalydeco)*

Addition – Brand

12784W *AZACITIDINE EUGIA, YG* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

13033Y *AZACITIDINE EUGIA, YG* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

13038F *AZACITIDINE EUGIA, YG* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

13039G *AZACITIDINE EUGIA, YG* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

13040H *AZACITIDINE EUGIA, YG* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

6100C *AZACITIDINE EUGIA, YG* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

6138C *AZACITIDINE EUGIA, YG* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

10084R *PLERIXAFOR EUGIA, YG* – **PLERIXAFOR**, plerixafor 24 mg/1.2 mL injection, 1.2 mL vial

Deletions

Deletion – Brand

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

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

12139X *Tracleer, JC* – **BOSENTAN**, bosentan 62.5 mg tablet, 60

12143D *Tracleer, JC* – **BOSENTAN**, bosentan 62.5 mg tablet, 60

12148J *Tracleer, JC* – **BOSENTAN**, bosentan 62.5 mg tablet, 60

6429J *Tracleer, JC* – **BOSENTAN**, bosentan 62.5 mg tablet, 60

12146G *Tracleer, JC* – **BOSENTAN**, bosentan 125 mg tablet, 60

6430K *Tracleer, JC* – **BOSENTAN**, bosentan 125 mg tablet, 60

6209T *Noumed Mycophenolate, VO* – **MYCOPHENOLATE**, mycophenolate mofetil 500 mg tablet, 50

Deletion – Note

13242Y **MEPOLIZUMAB**, mepolizumab 100 mg/mL injection, 1 mL pen device *(Nucala)*

6439X **PEGINTERFERON ALFA-2A**, peginterferon alfa-2a 135 microgram/0.5 mL injection, 4 x 0.5 mL syringes *(Pegasys)*

6449K **PEGINTERFERON ALFA-2A**, peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes *(Pegasys)*

10084R **PLERIXAFOR**, plerixafor 24 mg/1.2 mL injection, 1.2 mL vial *(Mozobil, PLERIXAFOR EUGIA, Plerixafor ARX)*

13244C **RUXOLITINIB**, ruxolitinib 5 mg tablet, 56 *(Jakavi)*

13231J **RUXOLITINIB**, ruxolitinib 10 mg tablet, 56 *(Jakavi)*

Deletion – Restriction

13242Y **MEPOLIZUMAB**, mepolizumab 100 mg/mL injection, 1 mL pen device *(Nucala)*

13244C **RUXOLITINIB**, ruxolitinib 5 mg tablet, 56 *(Jakavi)*

13231J **RUXOLITINIB**, ruxolitinib 10 mg tablet, 56 *(Jakavi)*

Alterations

Alteration – Note

11097C **IVACAFTOR**, ivacaftor 50 mg granules, 56 sachets *(Kalydeco)*

11109Q **IVACAFTOR**, ivacaftor 75 mg granules, 56 sachets *(Kalydeco)*

10175M **IVACAFTOR**, ivacaftor 150 mg tablet, 56 *(Kalydeco)*

11009K **RIOCIGUAT**, riociguat 500 microgram tablet, 42 *(Adempas)*

10990K **RIOCIGUAT**, riociguat 1 mg tablet, 42 *(Adempas)*

10974N **RIOCIGUAT**, riociguat 1.5 mg tablet, 42 *(Adempas)*

11012N **RIOCIGUAT**, riociguat 2 mg tablet, 42 *(Adempas)*

10985E **RIOCIGUAT**, riociguat 2.5 mg tablet, 42 *(Adempas)*

Alteration – Restriction

6232B **CICLOSPORIN**, ciclosporin 10 mg capsule, 60 *(Neoral 10)*

6352H **CICLOSPORIN**, ciclosporin 25 mg capsule, 30 *(APO-Ciclosporin, Cyclosporin Sandoz, Neoral 25)*

6353J **CICLOSPORIN**, ciclosporin 50 mg capsule, 30 *(APO-Ciclosporin, Cyclosporin Sandoz, Neoral 50)*

6354K **CICLOSPORIN**, ciclosporin 100 mg capsule, 30 *(APO-Ciclosporin, Cyclosporin Sandoz, Neoral 100)*

6125J **CICLOSPORIN**, ciclosporin 100 mg/mL oral liquid, 50 mL *(Neoral)*

11097C **IVACAFTOR**, ivacaftor 50 mg granules, 56 sachets *(Kalydeco)*

11109Q **IVACAFTOR**, ivacaftor 75 mg granules, 56 sachets *(Kalydeco)*

10175M **IVACAFTOR**, ivacaftor 150 mg tablet, 56 *(Kalydeco)*

11009K **RIOCIGUAT**, riociguat 500 microgram tablet, 42 *(Adempas)*

10990K **RIOCIGUAT**, riociguat 1 mg tablet, 42 *(Adempas)*

10974N **RIOCIGUAT**, riociguat 1.5 mg tablet, 42 *(Adempas)*

11012N **RIOCIGUAT**, riociguat 2 mg tablet, 42 *(Adempas)*

10985E **RIOCIGUAT**, riociguat 2.5 mg tablet, 42 *(Adempas)*

Advance Notices

1 August 2024

Deletion – Brand

12146G *Bosentan Cipla, LR* – **BOSENTAN**, bosentan 125 mg tablet, 60

6430K *Bosentan Cipla, LR* – **BOSENTAN**, bosentan 125 mg tablet, 60

11888Q *Cinacalcet Mylan, AF* – **CINACALCET**, cinacalcet 90 mg tablet, 28

9627Q *Cinacalcet Mylan, AF* – **CINACALCET**, cinacalcet 90 mg tablet, 28

6208R *CellCept, RO* – **MYCOPHENOLATE**, mycophenolate mofetil 250 mg capsule, 100

6209T *CellCept, RO* – **MYCOPHENOLATE**, mycophenolate mofetil 500 mg tablet, 50

Highly Specialised Drugs Program (Public Hospital)

Additions

Addition – Item

14155B **IVACAFTOR**, ivacaftor 25 mg granules, 56 sachets *(Kalydeco)*

14156C **IVACAFTOR**, ivacaftor 25 mg granules, 56 sachets *(Kalydeco)*

14148P **IVACAFTOR**, ivacaftor 50 mg granules, 56 sachets *(Kalydeco)*

14167P **IVACAFTOR**, ivacaftor 75 mg granules, 56 sachets *(Kalydeco)*

14153X **IVACAFTOR**, ivacaftor 150 mg tablet, 56 *(Kalydeco)*

Addition – Brand

12771E *AZACITIDINE EUGIA, YG* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

13028Q *AZACITIDINE EUGIA, YG* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

13036D *AZACITIDINE EUGIA, YG* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

13042K *AZACITIDINE EUGIA, YG* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

13044M *AZACITIDINE EUGIA, YG* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

9597D *AZACITIDINE EUGIA, YG* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

9598E *AZACITIDINE EUGIA, YG* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

10083Q *PLERIXAFOR EUGIA, YG* – **PLERIXAFOR**, plerixafor 24 mg/1.2 mL injection, 1.2 mL vial

Deletions

Deletion – Brand

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

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

12134P *Tracleer, JC* – **BOSENTAN**, bosentan 62.5 mg tablet, 60

12140Y *Tracleer, JC* – **BOSENTAN**, bosentan 62.5 mg tablet, 60

12145F *Tracleer, JC* – **BOSENTAN**, bosentan 62.5 mg tablet, 60

5618Q *Tracleer, JC* – **BOSENTAN**, bosentan 62.5 mg tablet, 60

12149K *Tracleer, JC* – **BOSENTAN**, bosentan 125 mg tablet, 60

5619R *Tracleer, JC* – **BOSENTAN**, bosentan 125 mg tablet, 60

9502D *Noumed Mycophenolate, VO* – **MYCOPHENOLATE**, mycophenolate mofetil 500 mg tablet, 50

Deletion – Note

13237Q **MEPOLIZUMAB**, mepolizumab 100 mg/mL injection, 1 mL pen device *(Nucala)*

9515T **PEGINTERFERON ALFA-2A**, peginterferon alfa-2a 135 microgram/0.5 mL injection, 4 x 0.5 mL syringes *(Pegasys)*

9516W **PEGINTERFERON ALFA-2A**, peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes *(Pegasys)*

10083Q **PLERIXAFOR**, plerixafor 24 mg/1.2 mL injection, 1.2 mL vial *(Mozobil, PLERIXAFOR EUGIA, Plerixafor ARX)*

13238R **RUXOLITINIB**, ruxolitinib 5 mg tablet, 56 *(Jakavi)*

13245D **RUXOLITINIB**, ruxolitinib 10 mg tablet, 56 *(Jakavi)*

Deletion – Restriction

13237Q **MEPOLIZUMAB**, mepolizumab 100 mg/mL injection, 1 mL pen device *(Nucala)*

13238R **RUXOLITINIB**, ruxolitinib 5 mg tablet, 56 *(Jakavi)*

13245D **RUXOLITINIB**, ruxolitinib 10 mg tablet, 56 *(Jakavi)*

Alterations

Alteration – Note

11105L **IVACAFTOR**, ivacaftor 50 mg granules, 56 sachets *(Kalydeco)*

11098D **IVACAFTOR**, ivacaftor 75 mg granules, 56 sachets *(Kalydeco)*

10170G **IVACAFTOR**, ivacaftor 150 mg tablet, 56 *(Kalydeco)*

11001B **RIOCIGUAT**, riociguat 500 microgram tablet, 42 *(Adempas)*

10976Q **RIOCIGUAT**, riociguat 1 mg tablet, 42 *(Adempas)*

10989J **RIOCIGUAT**, riociguat 1.5 mg tablet, 42 *(Adempas)*

10984D **RIOCIGUAT**, riociguat 2 mg tablet, 42 *(Adempas)*

11002C **RIOCIGUAT**, riociguat 2.5 mg tablet, 42 *(Adempas)*

Alteration – Restriction

5632K **CICLOSPORIN**, ciclosporin 10 mg capsule, 60 *(Neoral 10)*

5634M **CICLOSPORIN**, ciclosporin 25 mg capsule, 30 *(APO-Ciclosporin, Cyclosporin Sandoz, Neoral 25)*

5635N **CICLOSPORIN**, ciclosporin 50 mg capsule, 30 *(APO-Ciclosporin, Cyclosporin Sandoz, Neoral 50)*

5636P **CICLOSPORIN**, ciclosporin 100 mg capsule, 30 *(APO-Ciclosporin, Cyclosporin Sandoz, Neoral 100)*

5633L **CICLOSPORIN**, ciclosporin 100 mg/mL oral liquid, 50 mL *(Neoral)*

11105L **IVACAFTOR**, ivacaftor 50 mg granules, 56 sachets *(Kalydeco)*

11098D **IVACAFTOR**, ivacaftor 75 mg granules, 56 sachets *(Kalydeco)*

10170G **IVACAFTOR**, ivacaftor 150 mg tablet, 56 *(Kalydeco)*

11001B **RIOCIGUAT**, riociguat 500 microgram tablet, 42 *(Adempas)*

10976Q **RIOCIGUAT**, riociguat 1 mg tablet, 42 *(Adempas)*

10989J **RIOCIGUAT**, riociguat 1.5 mg tablet, 42 *(Adempas)*

10984D **RIOCIGUAT**, riociguat 2 mg tablet, 42 *(Adempas)*

11002C **RIOCIGUAT**, riociguat 2.5 mg tablet, 42 *(Adempas)*

Advance Notices

1 August 2024

Deletion – Brand

12149K *Bosentan Cipla, LR* – **BOSENTAN**, bosentan 125 mg tablet, 60

5619R *Bosentan Cipla, LR* – **BOSENTAN**, bosentan 125 mg tablet, 60

11885M *Cinacalcet Mylan, AF* – **CINACALCET**, cinacalcet 90 mg tablet, 28

5623Y *Cinacalcet Mylan, AF* – **CINACALCET**, cinacalcet 90 mg tablet, 28

9501C *CellCept, RO* – **MYCOPHENOLATE**, mycophenolate mofetil 250 mg capsule, 100

9502D *CellCept, RO* – **MYCOPHENOLATE**, mycophenolate mofetil 500 mg tablet, 50

Highly Specialised Drugs Program (Community Access)

Deletions

Deletion – Brand

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

Prescriber Bag

- **BENZATHINE BENZYLPENICILLIN**

benzathine benzylpenicillin 1.2 million units powder for injection [1 vial] (&) inert substance diluent [5 mL vial], 1 pack

	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
13801J NP	10	*511.47	[a] Benzylpenicillin Benzathine (Brancaster Pharma, UK) [OJ]	[a] Extencilline Benzathine Benzylpenicillin (France) [YO]

OR

benzathine benzylpenicillin tetrahydrate 1.2 million units (1016.6 mg)/2.3 mL injection, 10 x 2.3 mL syringes

	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
11755Q NP	1	335.51	[a] Bicillin L-A [PF]

General Pharmaceutical Benefits

▪ ADALIMUMAB

Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab prior to 1 June 2024 is considered to start their first cycle as of 1 June 2024.

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

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

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

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

(2) Grandfather patients (secukinumab only).

A patient who commenced treatment with secukinumab for moderate to severe hidradenitis suppurativa prior to 1 June 2024 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this restriction. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing/swapping therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response as defined in the restriction within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

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

Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

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

Note 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)

11529

Moderate to severe hidradenitis suppurativa

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated a response to treatment with this drug for this condition.

Treatment criteria:

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

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

A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.

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

13221W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*1108.39	31.60	[a] Adalicip [LR]	[a] Yuflyma [EW]

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

12330Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*1354.03	31.60	[a] Amgevita [XT] [a] Hyrimoz [SZ]	[a] Hadlima [RF] [a] Idacio [PK]

▪ ADALIMUMAB

Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab prior to 1 June 2024 is considered to start their first cycle as of 1 June 2024.

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

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

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

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

(2) Grandfather patients (secukinumab only).

A patient who commenced treatment with secukinumab for moderate to severe hidradenitis suppurativa prior to 1 June 2024 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this restriction. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing/swapping therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response as defined in the restriction within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

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.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to treatment with this drug for this condition.

Treatment criteria:

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.

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

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the Hidradenitis Suppurativa Clinical Response (HiSCR) result.

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

12448E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*1345.59	31.60	Humira [VE]

adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe

12408C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*1345.59	31.60	Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.
Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.
Treatment cycles:
Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab prior to 1 June 2024 is considered to start their first cycle as of 1 June 2024.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.
Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.
Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
Prescribing under the correct 'Treatment phase' listing for the authority application:
(1) Initial treatment.
Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.
(2) Grandfather patients (secukinumab only).
A patient who commenced treatment with secukinumab for moderate to severe hidradenitis suppurativa prior to 1 June 2024 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this restriction. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.
(3) Continuing treatment.
Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing/swapping therapy.
Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response as defined in the restriction within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

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

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

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: First continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to treatment with this drug for this condition.

Treatment criteria:

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.

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

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the Hidradenitis Suppurativa Clinical Response (HiSCR) result.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated a response to treatment with this drug for this condition.

Treatment criteria:

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.

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

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the Hidradenitis Suppurativa Clinical Response (HiSCR) result.

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

12414J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*1108.39	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

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

12369B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*1354.03	31.60	[a] Amgevita [XT] [a] Hyrimoz [SZ]	[a] Hadlima [RF] [a] Idacio [PK]

▪ ADALIMUMAB

Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab prior to 1 June 2024 is considered to start their first cycle as of 1 June 2024.

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

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

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

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

(2) Grandfather patients (secukinumab only).

A patient who commenced treatment with secukinumab for moderate to severe hidradenitis suppurativa prior to 1 June 2024 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this restriction. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the

restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.
(4) Changing/swapping therapy.
Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response as defined in the restriction within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

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.

Authority required

Moderate to severe hidradenitis suppurativa

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

Clinical criteria:

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR
- Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient) or Initial 2 (recommencement of treatment) - balance of supply

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

(1) a completed authority prescription form; and

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

(i) the Hurley stage grading; and

(ii) the AN count; and

(iii) the name of the antibiotic/s received for two separate courses each of three months; or

(iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the

prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 2 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply.

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

(1) a completed authority prescription form; and

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

(i) the Hurley stage grading; and

(ii) the AN count.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply.

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

(1) a completed authority prescription form; and

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

(i) the Hurley stage grading; and

(ii) the AN count.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

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

12450G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	..	..	*2014.38	31.60	Humira [VE]

adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe

12524E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	..	..	*2014.38	31.60	Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab prior to 1 June 2024 is considered to start their first cycle as of 1 June 2024.

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

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

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

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

(2) Grandfather patients (secukinumab only).

A patient who commenced treatment with secukinumab for moderate to severe hidradenitis suppurativa prior to 1 June 2024 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this restriction. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing/swapping therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response as defined in the restriction within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a

biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

Note Biosimilar prescribing policy
Prescribing of the biosimilar brand Amgevita, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

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

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

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

Authority required

Moderate to severe hidradenitis suppurativa

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

Clinical criteria:

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR
- Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient) or Initial 2 (recommencement of treatment) - balance of supply

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

(1) a completed authority prescription form; and

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

(i) the Hurley stage grading; and

(ii) the AN count; and

(iii) the name of the antibiotic/s received for two separate courses each of three months; or

(iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 2 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply.

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

(1) a completed authority prescription form; and

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

(i) the Hurley stage grading; and

(ii) the AN count.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply.

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

(1) a completed authority prescription form; and

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

(i) the Hurley stage grading; and

(ii) the AN count.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

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

12356H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3	..	..	*2027.04	31.60	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	[a] Idacio [PK]

▪ ADALIMUMAB

Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab prior to 1 June 2024 is considered to start their first cycle as of 1 June 2024.

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

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

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

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

(2) Grandfather patients (secukinumab only).

A patient who commenced treatment with secukinumab for moderate to severe hidradenitis suppurativa prior to 1 June 2024 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this restriction. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing/swapping therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response as defined in the restriction within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

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

Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Amgevita, Adalicip, Hadlima, Hyrimoz, Idacio or Yuflyma is encouraged for treatment naive patients.

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

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

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

Authority required

Moderate to severe hidradenitis suppurativa

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

Clinical criteria:

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR
- Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient) or Initial 2 (recommencement of treatment) - balance of supply

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

(1) a completed authority prescription form; and

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

(i) the Hurley stage grading; and

(ii) the AN count; and

(iii) the name of the antibiotic/s received for two separate courses each of three months; or

(iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 2 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply.

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

(1) a completed authority prescription form; and

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

(i) the Hurley stage grading; and

(ii) the AN count.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply.

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

(1) a completed authority prescription form; and

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

(i) the Hurley stage grading; and

(ii) the AN count.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

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

12454L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3	..	..	*1658.58	31.60	[a] Adalicip [LR] [a] Yuflyma [EW]	[a] Humira [VE]

▪ ALOGLIPTIN

Note Definition:

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

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

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)

15261

Diabetes mellitus type 2

Clinical criteria:

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

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

alogliptin 6.25 mg tablet, 28

2944Y (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	51.48	31.60	Nesina [TK]

alogliptin 12.5 mg tablet, 28

2933J (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	51.48	31.60	Nesina [TK]

alogliptin 25 mg tablet, 28

2986E (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	51.48	31.60	Nesina [TK]

▪ ALOGLIPTIN

Note Definition:

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

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

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)

15287

Diabetes mellitus type 2

Clinical criteria:

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

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

alogliptin 6.25 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13897K NP	2	5	..	*89.97	31.60	Nesina [TK]

alogliptin 12.5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13977P NP	2	5	..	*89.97	31.60	Nesina [TK]

alogliptin 25 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13953J NP	2	5	..	*89.97	31.60	Nesina [TK]

▪ ALOGLIPTIN + METFORMIN

Note Definition:

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

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

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)

15276

Diabetes mellitus type 2

Clinical criteria:

- The condition must be inadequately responsive to metformin.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

alogliptin 12.5 mg + metformin hydrochloride 500 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10033C NP	1	5	..	52.91	31.60	Nesina Met 12.5/500 [TK]

alogliptin 12.5 mg + metformin hydrochloride 850 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10032B NP	1	5	..	53.88	31.60	Nesina Met 12.5/850 [TK]

alogliptin 12.5 mg + metformin hydrochloride 1 g tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10035E NP	1	5	..	54.27	31.60	Nesina Met 12.5/1000 [TK]

▪ ALOGLIPTIN + METFORMIN

Note Definition:

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

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

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

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)

15288

Diabetes mellitus type 2

Clinical criteria:

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

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

alogliptin 12.5 mg + metformin hydrochloride 500 mg tablet, 56

14062D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*92.83	31.60	Nesina Met 12.5/500 [TK]

NP

alogliptin 12.5 mg + metformin hydrochloride 850 mg tablet, 56

14061C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*94.77	31.60	Nesina Met 12.5/850 [TK]

NP

alogliptin 12.5 mg + metformin hydrochloride 1 g tablet, 56

13989G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*95.55	31.60	Nesina Met 12.5/1000 [TK]

NP

▪ APREMILAST

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)

15326

Severe chronic plaque psoriasis

Clinical criteria:

- Patient must not have achieved adequate response after at least 6 weeks of treatment with methotrexate prior to initiating treatment with this drug; OR
- Patient must have a contraindication to methotrexate according to the Therapeutic Goods Administration (TGA) approved Product Information; OR
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate, **AND**
- The condition must have caused significant interference with quality of life, **AND**
- Patient must not be undergoing concurrent PBS-subsidised treatment for psoriasis with each of: (i) a biological medicine, (ii) ciclosporin, (iii) deucravacitinib.

Treatment criteria:

- Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) a rheumatologist, (iii) general physician; OR
- Must be treated by a medical practitioner in consultation with one of the above specialist types who is either an accredited: (i) dermatology registrar, (ii) rheumatology registrar; OR
- Must be treated by a general practitioner where there is agreement to continue treatment (not initiate treatment) with one of the above practitioner types.

Population criteria:

- Patient must be at least 18 years of age.

For patients who do not demonstrate an adequate response to apremilast, a Psoriasis Area and Severity Index (PASI) assessment must be completed, preferably while on treatment, but no longer than 4 weeks following the cessation of treatment. This assessment will be required for patients who transition to 'biological medicines' for the treatment of 'severe chronic plaque psoriasis'.

This assessment must be documented in the patient's medical records.

apremilast 30 mg tablet, 56

12223H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	653.71	31.60	Otezla [AN]

apremilast 10 mg tablet [4] (&) apremilast 20 mg tablet [4] (&) apremilast 30 mg tablet [19], 27

12218C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	273.20	31.60	Otezla [AN]

▪ BENZATHINE BENZYLPENICILLIN

Note Pharmaceutical benefits that have the brand Benzylpenicillin Benzathine (Brancaster Pharma, UK) and Extencilline Benzathine Benzylpenicillin (France) may be substituted for pharmaceutical benefits that have the brand Bicillin L-A in case of shortage.

benzathine benzylpenicillin 1.2 million units powder for injection [1 vial] (&) inert substance diluent [5 mL vial], 1 pack

13790T DP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10	..	..	*511.47	31.60	[a] Benzylpenicillin Benzathine (Brancaster Pharma, UK) [OJ]	[a] Extencilline Benzathine Benzylpenicillin (France) [YO]

benzathine benzylpenicillin 1.2 million units powder for injection [1 vial] (&) inert substance diluent [5 mL vial], 1 pack

13816E NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10	..	..	*511.47	31.60	[a] Benzylpenicillin Benzathine (Brancaster Pharma, UK) [OJ]	[a] Extencilline Benzathine Benzylpenicillin (France) [YO]

benzathine benzylpenicillin tetrahydrate 1.2 million units (1016.6 mg)/2.3 mL injection, 10 x 2.3 mL syringes

2267H NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	335.51	31.60	[a] Bicillin L-A [PF]

benzathine benzylpenicillin tetrahydrate 1.2 million units (1016.6 mg)/2.3 mL injection, 10 x 2.3 mL syringes

5027N DP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	335.51	31.60	[a] Bicillin L-A [PF]

▪ BUDESONIDE + FORMOTEROL

Note Patient must be aged 12 years or over.

Note This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD) or for allergen-induced or exercise-induced bronchoconstriction in the absence of asthma.

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

Authority required (STREAMLINED)

10464

Mild asthma

Clinical criteria:

- Patient must have asthma and require an anti-inflammatory reliever therapy, **AND**
- Patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA).

Device (inhaler) technique should be reviewed at each clinical visit and before initiating treatment with this medicine.

budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 60 actuations

14166N NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡2	2	..	*37.01	31.60	Bufomix Easyhaler 200/6 [OX]

▪ BUDESONIDE + FORMOTEROL

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

Note This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

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

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

10538

Asthma

Clinical criteria:

- Patient must have failed PBS-subsidised fluticasone proprionate and salmeterol as a fixed dose combination for this condition.

Treatment criteria:

- Must be treated by a respiratory physician; OR
- Must be treated by a paediatrician.

budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 60 actuations

14159F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡2	5	..	*37.01	31.60	Bufomix Easyhaler 200/6 [OX]

▪ BUDESONIDE + FORMOTEROL

Note Patient must be aged 12 years or over.

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

Note This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

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

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

7970

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 60 actuations

14151T NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡2	5	..	*37.01	31.60	Bufomix Easyhaler 200/6 [OX]

▪ DAPAGLIFLOZIN

Note Definition:

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

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

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)

15311

Diabetes mellitus type 2

Clinical criteria:

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

Treatment criteria:

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

dapagliflozin 10 mg tablet, 28

10011X NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	55.58	31.60	Forxiga [AP]

▪ DAPAGLIFLOZIN

Note Definition:

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

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

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)

15265

Diabetes mellitus type 2

Clinical criteria:

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

Treatment criteria:

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

dapagliflozin 10 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13844P NP	2	5	..	*98.17	31.60	Forxiga [AP]

▪ DAPAGLIFLOZIN + METFORMIN

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

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

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)

15289

Diabetes mellitus type 2

Clinical criteria:

- The condition must be inadequately responsive to metformin.

Treatment criteria:

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

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

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10510E NP	1	5	..	58.54	31.60	Xigduo XR 5/1000 [AP]

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

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10515K NP	1	5	..	57.11	31.60	Xigduo XR 10/1000 [AP]

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

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10516L NP	1	5	..	56.34	31.60	Xigduo XR 10/500 [AP]

▪ DAPAGLIFLOZIN + METFORMIN

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

(b) Red cell transfusion within the previous 3 months.
Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

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

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)

15267

Diabetes mellitus type 2

Clinical criteria:

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

Treatment criteria:

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

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

13851B (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*104.09	31.60	Xigduo XR 5/1000 [AP]

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

13875G (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*101.23	31.60	Xigduo XR 10/1000 [AP]

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

14028H (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*99.69	31.60	Xigduo XR 10/500 [AP]

▪ DEUCRAVACITINIB

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)

15330

Severe chronic plaque psoriasis

Clinical criteria:

- Patient must not have achieved adequate response after at least 6 weeks of treatment with methotrexate prior to initiating treatment with this drug; OR
- Patient must have a contraindication to methotrexate according to the Therapeutic Goods Administration (TGA) approved Product Information; OR
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate, **AND**
- The condition must have caused significant interference with quality of life, **AND**
- Patient must not be undergoing concurrent PBS-subsidised treatment for psoriasis with each of: (i) a biological medicine, (ii) ciclosporin, (iii) apremilast.

Treatment criteria:

- Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) a rheumatologist, (iii) general physician; OR
- Must be treated by a medical practitioner in consultation with one of the above specialist types who is either an accredited: (i) dermatology registrar, (ii) rheumatology registrar; OR
- Must be treated by a general practitioner where there is agreement to continue treatment (not initiate treatment) with one of the above practitioner types.

Population criteria:

- Patient must be at least 18 years of age.

For patients who do not demonstrate an adequate response to apremilast, a Psoriasis Area and Severity Index (PASI) assessment must be completed, preferably while on treatment, but no longer than 4 weeks following the cessation of treatment. This assessment will be required for patients who transition to 'biological medicines' for the treatment of 'severe chronic plaque psoriasis'.

This assessment must be documented in the patient's medical records.

deucravacitinib 6 mg tablet, 28

13649J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1259.52	31.60	Sotyktu [BQ]

▪ DULAGLUTIDE

Note Special Pricing Arrangements apply.

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

Note Where an SGLT2 inhibitor is being accessed through a PBS indication other than diabetes, the clinical criterion excluding concomitant treatment with an SGLT2 inhibitor is in relation to diabetes mellitus type 2 only.

Authority required (STREAMLINED)

15263

Diabetes mellitus type 2

Treatment Phase: Subsequent PBS-prescriptions for any GLP-1 receptor agonist

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment for type 2 diabetes mellitus with any of: an SGLT2 inhibitor, a DPP4 inhibitor, another GLP-1 receptor agonist.

dulaglutide 1.5 mg/0.5 mL injection, 4 x 0.5 mL pen devices

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14150R NP	1	5	..	133.80	31.60	Trulicity [LY]

▪ DULAGLUTIDE

Note Special Pricing Arrangements apply.

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

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

Note Where an SGLT2 inhibitor is being accessed through a PBS indication other than diabetes, the clinical criterion excluding concomitant treatment with an SGLT2 inhibitor is in relation to diabetes mellitus type 2 only.

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

Diabetes mellitus type 2

Treatment Phase: First PBS-prescription for this drug

Clinical criteria:

- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin, **AND**
- Patient must not have achieved a clinically meaningful glycaemic response with an SGLT2 inhibitor; OR
- Patient must have a contraindication/intolerance requiring treatment discontinuation of an SGLT2 inhibitor.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment for type 2 diabetes mellitus with any of: an SGLT2 inhibitor, a DPP4 inhibitor, another GLP-1 receptor agonist.

dulaglutide 1.5 mg/0.5 mL injection, 4 x 0.5 mL pen devices

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11364D NP	1	5	..	133.80	31.60	Trulicity [LY]

▪ EMPAGLIFLOZIN

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

Note Abbreviations used in the restriction are as follows:
SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

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)

15311

Diabetes mellitus type 2

Clinical criteria:

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

Treatment criteria:

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

empagliflozin 10 mg tablet, 30

10206E NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	60.77	31.60	Jardiance [BY]

empagliflozin 25 mg tablet, 30

10202Y NP

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

▪ EMPAGLIFLOZIN

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

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

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)

15265

Diabetes mellitus type 2

Clinical criteria:

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

Treatment criteria:

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

empagliflozin 10 mg tablet, 30

13845Q NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*108.55	31.60	Jardiance [BY]

empagliflozin 25 mg tablet, 30

13920P NP

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

▪ EMPAGLIFLOZIN + LINAGLIPTIN

Note Definition:
A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.
Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances

applies:
(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),
(b) Red cell transfusion within the previous 3 months.
Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

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

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)

15269

Diabetes mellitus type 2

Clinical criteria:

- The treatment must be in combination with at least metformin, **AND**
- The condition must be inadequately responsive to dual therapy consisting of metformin with either: a DDP-4 inhibitor, an SGLT2 inhibitor.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor, another DPP4 inhibitor.

empagliflozin 10 mg + linagliptin 5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11269D NP	1	5	..	82.54	31.60	Glyxambi [BY]

empagliflozin 25 mg + linagliptin 5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11303X NP	1	5	..	82.54	31.60	Glyxambi [BY]

▪ EMPAGLIFLOZIN + LINAGLIPTIN

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

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

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)

15270

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 at least metformin, **AND**
- The condition must be inadequately responsive to dual therapy consisting of metformin with either: a DDP-4 inhibitor, an SGLT2 inhibitor.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor, another DPP4 inhibitor.

empagliflozin 10 mg + linagliptin 5 mg tablet, 30

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

empagliflozin 25 mg + linagliptin 5 mg tablet, 30

13958P

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

NP

▪ EMPAGLIFLOZIN + METFORMIN

Note Definition:

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

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

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)

15289

Diabetes mellitus type 2

Clinical criteria:

- The condition must be inadequately responsive to metformin.

Treatment criteria:

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

empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60

10626G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	62.61	31.60	Jardiamet 5 mg/500 mg [BY]

NP

empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60

10627H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	64.13	31.60	Jardiamet 5 mg/1000 mg [BY]

NP

empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60

10633P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	62.61	31.60	Jardiamet 12.5 mg/500 mg [BY]

NP

empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60

10677Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	64.13	31.60	Jardiamet 12.5 mg/1000 mg [BY]

NP

▪ EMPAGLIFLOZIN + METFORMIN

Note Definition:

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

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

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)

15267

Diabetes mellitus type 2

Clinical criteria:

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

Treatment criteria:

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

empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14029J NP	2	5	..	*112.23	31.60	Jardiamet 5 mg/500 mg [BY]

empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13852C NP	2	5	..	*115.39	31.60	Jardiamet 5 mg/1000 mg [BY]

empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13903R NP	2	5	..	*112.23	31.60	Jardiamet 12.5 mg/500 mg [BY]

empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13987E NP	2	5	..	*115.39	31.60	Jardiamet 12.5 mg/1000 mg [BY]

▪ INCLISIRAN

Note Monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) medications are evolocumab or alirocumab.

Note Authority applications for increased repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone to Services Australia on 1800 888 333.

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

15065

Familial heterozygous hypercholesterolaemia

Treatment Phase: Continuing treatment with this drug or switching treatment from a monoclonal antibody inhibiting proprotein coverase subtilisin kexin type 9 (PSCK9) for this PBS indication

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have previously received PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication.

Authority required (STREAMLINED)

15110

Non-familial hypercholesterolaemia

Treatment Phase: Continuing treatment with this drug or switching treatment from a monoclonal antibody inhibiting proprotein coverase subtilisin kexin type 9 (PSCK9) for this PBS indication

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have previously received PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication.

inclisiran 284 mg/1.5 mL injection, 1.5 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14087K	1	..	..	1849.00	31.60	Leqvio [NV]

▪ INCLISIRAN

Note Monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) medications are evolocumab or alirocumab.

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

Familial heterozygous hypercholesterolaemia

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The condition must have been confirmed by genetic testing; OR
- The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 6, **AND**
- Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre in the presence of symptomatic atherosclerotic cardiovascular disease; OR
- Patient must have an LDL cholesterol level in excess of 5 millimoles per litre, **AND**
- Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; OR
- Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; OR
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information, **AND**
- Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise; OR
- Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication.

Treatment criteria:

- Must be treated by a specialist physician; OR
- Must be treated by a physician who has consulted a specialist physician.

Symptomatic atherosclerotic cardiovascular disease is defined as:

(i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or

(ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or

(iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).

The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be stated at the time of application, documented in the patient's medical records and must be no more than 8 weeks old.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retrial should not occur until CK has returned to normal.

In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.

The following must be stated at the time of application and documented in the patient's medical records:

(i) the qualifying Dutch Lipid Clinic Network Score; or

(ii) the result of genetic testing confirming a diagnosis of familial heterozygous hypercholesterolaemia

One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment:

(i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or

(ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or

(iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.

Authority required

Non-familial hypercholesterolaemia

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have symptomatic atherosclerotic cardiovascular disease, **AND**
- Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre, **AND**
- Patient must have atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); OR
- Patient must have severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; OR
- Patient must have had at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher, **AND**
- Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; OR
- Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; OR
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information, **AND**
- Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise; OR
- Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication.

Treatment criteria:

- Must be treated by a specialist physician; OR
- Must be treated by a physician who has consulted a specialist physician.

Symptomatic atherosclerotic cardiovascular disease is defined as:

(i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or

(ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or

(iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).

The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be stated at the time of application, documented in the patient's medical records and must be no more than 8 weeks old.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retrial should not occur until CK has returned to normal.

In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.

One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment:

(i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or

(ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or

(iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.

One or more of the following must be stated at the time of application and documented in the patient's medical records regarding the presence of cardiovascular disease or high risk of experiencing a cardiovascular event:

(i) atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); or
(ii) severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; or
(iii) history of at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; or
(iv) diabetes mellitus with microalbuminuria; or
(v) diabetes mellitus and age 60 years or more; or
(vi) Aboriginal or Torres Strait Islander with diabetes mellitus; or
(vii) a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher.

inclisiran 284 mg/1.5 mL injection, 1.5 mL syringe

14101E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	1849.00	31.60	Leqvio [NV]

▪ INCLISIRAN

Note Monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) medications are evolocumab or alirocumab.

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.

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

Authority required

Familial heterozygous hypercholesterolaemia

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

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 April 2024, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The condition must have been confirmed by genetic testing prior to starting non-PBS-subsidised treatment with this drug for this condition; OR
- The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 6 prior to starting non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had an LDL cholesterol level in excess of 1.8 millimoles per litre in the presence of symptomatic atherosclerotic cardiovascular disease at the time non-PBS-subsidised treatment with this drug for this condition was initiated; OR
- Patient must have had an LDL cholesterol level in excess of 5 millimoles per litre at the time non-PBS-subsidised treatment with this drug for this condition was initiated, **AND**
- Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have developed a clinically important product-related adverse event necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information, **AND**
- Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication.

Treatment criteria:

- Must be treated by a specialist physician; OR
- Must be treated by a physician who has consulted a specialist physician.

Symptomatic atherosclerotic cardiovascular disease is defined as:

(i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or

(ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or

(iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).

The qualifying LDL cholesterol level must have been measured following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events), must be stated at the time of application, documented in the patient's medical records and must have been no more than 8 weeks old at the time non-PBS-subsidised treatment with this drug for this condition was initiated.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

If treatment with atorvastatin or rosuvastatin resulted in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must have been treated with the alternative statin (atorvastatin or rosuvastatin) unless there was a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should have occurred after a washout period of at least 4 weeks, or if the creatine kinase (CK) level was elevated, the retrial should not have occurred until CK had returned to normal.

In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.

The following must be stated at the time of application and documented in the patient's medical records:

(i) the qualifying Dutch Lipid Clinic Network Score; or

(ii) the result of genetic testing confirming a diagnosis of familial heterozygous hypercholesterolaemia

One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment:

(i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or

(ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or

(iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Authority required

Non-familial hypercholesterolaemia

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

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 April 2024, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have had symptomatic atherosclerotic cardiovascular disease prior to starting non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had an LDL cholesterol level in excess of 1.8 millimoles per litre prior to starting non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories) prior to starting non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have had severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels prior to starting non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have had at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years prior to starting non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have had diabetes mellitus with microalbuminuria prior to starting non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have had diabetes mellitus and be aged 60 years of more prior to starting non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus that was present prior to starting non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have had a Thrombolysis in Myocardial Infarction (TIMI) Risk Score for Secondary Prevention of 4 or higher prior to starting non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have developed a clinically important product-related adverse event necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information, **AND**
- Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication.

Treatment criteria:

- Must be treated by a specialist physician; OR
- Must be treated by a physician who has consulted a specialist physician.

Symptomatic atherosclerotic cardiovascular disease is defined as:

(i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or

(ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or

(iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).

The qualifying LDL cholesterol level must have been measured following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events), must be stated at the time of application, documented in the patient's medical records and must have been no more than 8 weeks old at the time non-PBS-subsidised treatment with this drug for this condition was initiated.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

If treatment with atorvastatin or rosuvastatin resulted in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must have been treated with the alternative statin (atorvastatin or rosuvastatin) unless there was a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should have occurred after a washout period of at least 4 weeks, or if the creatine kinase (CK) level was elevated, the retrial should not have occurred until CK had returned to normal.

In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.

One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment:

(i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or

(ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or

(iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.

One or more of the following must be stated at the time of application and documented in the patient's medical records regarding the presence of cardiovascular disease or high risk of experiencing a cardiovascular event:

(i) atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); or

(ii) severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; or

(iii) history of at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; or

(iv) diabetes mellitus with microalbuminuria; or

(v) diabetes mellitus and age 60 years or more; or

(vi) Aboriginal or Torres Strait Islander with diabetes mellitus; or

(vii) a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

inclisiran 284 mg/1.5 mL injection, 1.5 mL syringe

14152W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	1849.00	31.60	Leqvio [NV]

▪ LINAGLIPTIN

Note Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),

(b) Red cell transfusion within the previous 3 months.

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

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

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)

15261

Diabetes mellitus type 2

Clinical criteria:

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

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

linagliptin 5 mg tablet, 30

3387G NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	59.08	31.60	Trajenta [BY]

▪ LINAGLIPTIN

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

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

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)

15287

Diabetes mellitus type 2

Clinical criteria:

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

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

linagliptin 5 mg tablet, 30

13954K NP

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

▪ LINAGLIPTIN + METFORMIN

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

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

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)

15276

Diabetes mellitus type 2

Clinical criteria:

- The condition must be inadequately responsive to metformin.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10038H NP	1	5	..	63.12	31.60	Trajentamet [BY]

linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10045Q NP	1	5	..	64.19	31.60	Trajentamet [BY]

linagliptin 2.5 mg + metformin hydrochloride 1 g tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10044P NP	1	5	..	64.63	31.60	Trajentamet [BY]

▪ LINAGLIPTIN + METFORMIN

Note Definition:

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

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

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)

15288

Diabetes mellitus type 2

Clinical criteria:

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

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13959Q NP	2	5	..	*113.27	31.60	Trajentamet [BY]

linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14065G NP	2	5	..	*115.51	31.60	Trajentamet [BY]

linagliptin 2.5 mg + metformin hydrochloride 1 g tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13879L NP	2	5	..	*116.43	31.60	Trajentamet [BY]

▪ MEDROXYPROGESTERONE

Note Pharmaceutical benefits that have the form medroxyprogesterone acetate 150 mg/mL injection, 1 mL syringe and pharmaceutical benefits that have the form medroxyprogesterone acetate 150 mg/mL injection, 1 mL vial are equivalent for the purposes of substitution.

medroxyprogesterone acetate 150 mg/mL injection, 1 mL vial

3118D NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	27.12	28.52	[a] Depo-Ralovera [FZ]
		[B]7.00	34.12	28.52	[a] Depo-Provera [PF]

medroxyprogesterone acetate 150 mg/mL injection, 1 mL syringe

14160G NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	27.12	28.52	[a] Depo-Provera [PF]

▪ OSIMERTINIB

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

Stage IB, II or IIIA non-small cell lung cancer

Treatment Phase: Adjuvant therapy

Population criteria:

- Patient must be continuing existing PBS-subsidised treatment with this drug; OR
- Patient must be both: (i) transitioning from existing non-PBS to PBS-subsidised supply of this drug, (ii) untreated with EGFR-TKI at the time this drug was initiated.

Clinical criteria:

- The treatment must be for the purpose of adjuvant therapy following surgical resection, **AND**
- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material, **AND**
- Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug. **AND**
- The treatment must be commenced within 26 weeks of surgery, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

Treatment criteria:

- Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) 3 years in total for this condition from the first administered dose; mark any remaining repeat prescriptions with the word 'cancelled'; where (i)/(ii) has occurred.

PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

osimertinib 40 mg tablet, 30

14162J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	7581.63	31.60	Tagrisso [AP]

▪ OSIMERTINIB

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

Stage IB, II or IIIA non-small cell lung cancer

Treatment Phase: Adjuvant therapy

Population criteria:

- Patient must be both: (i) initiating treatment, (ii) untreated with EGFR-TKI for non small cell lung cancer; OR
- Patient must be continuing existing PBS-subsidised treatment with this drug; OR
- Patient must be both: (i) transitioning from existing non-PBS to PBS-subsidised supply of this drug, (ii) untreated with EGFR-TKI at the time this drug was initiated.

Clinical criteria:

- The treatment must be for the purpose of adjuvant therapy following surgical resection, **AND**
- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material, **AND**
- Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug. **AND**
- The treatment must be commenced within 26 weeks of surgery, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

Treatment criteria:

- Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) 3 years in total for this condition from the first administered dose; mark any remaining repeat prescriptions with the word 'cancelled'; where (i)/(ii) has occurred.

PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

osimertinib 80 mg tablet, 30

14168Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	7581.63	31.60	Tagrisso [AP]

▪ OSIMERTINIB

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

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment of second-line EGFR tyrosine kinase inhibitor therapy

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- 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.

Treatment criteria:

- Patient must be undergoing continuing treatment with this drug as second-line therapy (i.e. there are 2 Continuing treatment listings for this drug - ensure the correct Continuing treatment restriction is being accessed).

PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

osimertinib 40 mg tablet, 30

11620N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	7581.63	31.60	Tagrisso [AP]

▪ OSIMERTINIB

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

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

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

Note Special Pricing Arrangements apply.

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment of first-line EGFR tyrosine kinase inhibitor therapy

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 receiving treatment with this drug for this condition.

Treatment criteria:

- Patient must be undergoing continuing treatment with this drug as first-line therapy (i.e. there are 2 Continuing treatment listings for this drug - ensure the correct Continuing treatment restriction is being accessed).

PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

osimertinib 40 mg tablet, 30

12233W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	7581.63	31.60	Tagrisso [AP]

▪ OSIMERTINIB

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

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment as second-line EGFR tyrosine kinase inhibitor therapy

Clinical criteria:

- Patient must not have previously received this drug for this condition, **AND**

- The treatment must be as monotherapy, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The condition must have progressed on or after prior epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) therapy as first line treatment for this condition, **AND**
- Patient must have evidence of EGFR T790M mutation in tumour material at the point of progression on or after first line EGFR TKI treatment.

PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment of second-line EGFR tyrosine kinase inhibitor therapy

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- 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.

Treatment criteria:

- Patient must be undergoing continuing treatment with this drug as second-line therapy (i.e. there are 2 Continuing treatment listings for this drug - ensure the correct Continuing treatment restriction is being accessed).

PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

osimertinib 80 mg tablet, 30

11622Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	7581.63	31.60	Tagrisso [AP]

▪ OSIMERTINIB

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

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment as first-line epidermal growth factor receptor tyrosine kinase inhibitor therapy

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR
- Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal.

Population criteria:

- Patient must have evidence in tumour material of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors.

PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment of first-line EGFR tyrosine kinase inhibitor therapy

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 receiving treatment with this drug for this condition.

Treatment criteria:

- Patient must be undergoing continuing treatment with this drug as first-line therapy (i.e. there are 2 Continuing treatment listings for this drug - ensure the correct Continuing treatment restriction is being accessed).

PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

osimertinib 80 mg tablet, 30

12232T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	7581.63	31.60	Tagrisso [AP]

▪ PIOGLITAZONE

Restricted benefit

Diabetes mellitus type 2

pioglitazone 15 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8694N NP	1	5	..	19.63	21.03	[a] Acpio 15 [RF] [a] Actos [EW] [a] Vexazone [AF]	[a] Actaze [RW] [a] APOTEX-Pioglitazone [TX]

pioglitazone 30 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8695P NP	1	5	..	23.22	24.62	[a] Acpio 30 [RF] [a] Actos [EW] [a] Vexazone [AF]	[a] Actaze [RW] [a] APOTEX-Pioglitazone [TX]

pioglitazone 45 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8696Q NP	1	5	..	26.29	27.69	[a] Acpio 45 [RF] [a] Actos [EW] [a] Vexazone [AF]	[a] Actaze [RW] [a] APOTEX-Pioglitazone [TX]

▪ PIOGLITAZONE

Restricted benefit

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.

pioglitazone 15 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13898L NP	2	5	..	*26.27	27.67	[a] Acpio 15 [RF] [a] Actos [EW] [a] Vexazone [AF]	[a] Actaze [RW] [a] APOTEX-Pioglitazone [TX]

pioglitazone 30 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13921Q NP	2	5	..	*33.45	31.60	[a] Acpio 30 [RF] [a] Actos [EW] [a] Vexazone [AF]	[a] Actaze [RW] [a] APOTEX-Pioglitazone [TX]

pioglitazone 45 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
14057W NP	2	5	..	*39.59	31.60	[a] Acpio 45 [RF] [a] Actos [EW] [a] Vexazone [AF]	[a] Actaze [RW] [a] APOTEX-Pioglitazone [TX]

▪ SAXAGLIPTIN

Note Definition:

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

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

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)

15261

Diabetes mellitus type 2

Clinical criteria:

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

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

saxagliptin 5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8983T NP	1	5	..	56.01	31.60	Onglyza [AP]

saxagliptin 2.5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10128C NP	1	5	..	56.01	31.60	Onglyza [AP]

▪ SAXAGLIPTIN

Note Definition:

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

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

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)

15287

Diabetes mellitus type 2

Clinical criteria:

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

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

saxagliptin 5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13923T NP	2	5	..	*99.03	31.60	Onglyza [AP]

saxagliptin 2.5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13895H NP	2	5	..	*99.03	31.60	Onglyza [AP]

▪ SAXAGLIPTIN + DAPAGLIFLOZIN

Note Definition:

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

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

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)

15269

Diabetes mellitus type 2

Clinical criteria:

- The treatment must be in combination with at least metformin, **AND**
- The condition must be inadequately responsive to dual therapy consisting of metformin with either: a DDP-4 inhibitor, an SGLT2 inhibitor.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor, another DPP4 inhibitor.

saxagliptin 5 mg + dapagliflozin 10 mg tablet, 28

11286B NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	76.25	31.60	Qtern 5/10 [AP]

▪ SAXAGLIPTIN + DAPAGLIFLOZIN

Note Definition:

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

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

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)

15270

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 at least metformin, **AND**
- The condition must be inadequately responsive to dual therapy consisting of metformin with either: a DDP-4 inhibitor, an SGLT2 inhibitor.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor, another DPP4 inhibitor.

saxagliptin 5 mg + dapagliflozin 10 mg tablet, 28

13855F NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*140.83	31.60	Qtern 5/10 [AP]

▪ SAXAGLIPTIN + METFORMIN

Note Definition:

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

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

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)

15276

Diabetes mellitus type 2

Clinical criteria:

- The condition must be inadequately responsive to metformin.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

saxagliptin 5 mg + metformin hydrochloride 500 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10055F NP	1	5	..	59.03	31.60	Kombiglyze XR 5/500 [AP]

saxagliptin 5 mg + metformin hydrochloride 1 g modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10051B NP	1	5	..	59.78	31.60	Kombiglyze XR 5/1000 [AP]

saxagliptin 2.5 mg + metformin hydrochloride 1 g modified release tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10048W NP	1	5	..	61.19	31.60	Kombiglyze XR 2.5/1000 [AP]

▪ SAXAGLIPTIN + METFORMIN

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

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

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)

15288

Diabetes mellitus type 2

Clinical criteria:

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

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

saxagliptin 5 mg + metformin hydrochloride 500 mg modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14030K NP	2	5	..	*105.07	31.60	Kombiglyze XR 5/500 [AP]

saxagliptin 5 mg + metformin hydrochloride 1 g modified release tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13876H NP	2	5	..	*106.57	31.60	Kombiglyze XR 5/1000 [AP]

saxagliptin 2.5 mg + metformin hydrochloride 1 g modified release tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13880M NP	2	5	..	*109.39	31.60	Kombiglyze XR 2.5/1000 [AP]

▪ SECUKINUMAB

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

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

Note Special Pricing Arrangements apply.

Authority required

Moderate to severe hidradenitis suppurativa

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

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment.

Treatment criteria:

- Must be treated by a dermatologist.

secukinumab 150 mg/mL injection, 2 x 1 mL pen devices

14164L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1404.60	31.60	Cosentyx [NV]

▪ SECUKINUMAB

Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab prior to 1 June 2024 is considered to start their first cycle as of 1 June 2024.

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

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

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

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

(2) Grandfather patients (secukinumab only).

A patient who commenced treatment with secukinumab for moderate to severe hidradenitis suppurativa prior to 1 June 2024 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this restriction. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing/swapping therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response as defined in the restriction within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

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

Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

Note Special Pricing Arrangements apply.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to treatment with this drug for this condition.

Treatment criteria:

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.

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

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the Hidradenitis Suppurativa Clinical Response (HiSCR) result.

Authority required

Moderate to severe hidradenitis suppurativa

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

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 June 2024, **AND**
- Patient must have had a Hurley stage II or III with an abscess and inflammatory nodule (AN) count greater than or equal to 3 prior to starting treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to treatment by achieving Hidradenitis Suppurativa Clinical Response (HiSCR) after 12 weeks of treatment if the patient has been treated with this drug for this condition for 12 weeks or longer, **AND**
- Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Assessment of disease severity must not have been more than 4 weeks old at the time treatment with this drug was initiated.

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

(a) a completed authority prescription form; and

(b) completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:

(i) the Hurley stage grading; and

(ii) the AN count; and

(iii) the name of the antibiotic/s received for two separate courses each of three months; or

(iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics

(v) the Hidradenitis Suppurativa Clinical Response (HiSCR) result if the patient has received 12 weeks or more of treatment.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

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

secukinumab 150 mg/mL injection, 2 x 1 mL pen devices

14146M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1404.60	31.60	Cosentyx [NV]

▪ SECUKINUMAB

Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab prior to 1 June 2024 is considered to start their first cycle as of 1 June 2024.

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

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

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

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

(2) Grandfather patients (secukinumab only).

A patient who commenced treatment with secukinumab for moderate to severe hidradenitis suppurativa prior to 1 June 2024 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this restriction. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing/swapping therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response as defined in the restriction within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for

continuing treatment must be assessed according to these revised baseline measurements.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

Note Special Pricing Arrangements apply.

Authority required

Moderate to severe hidradenitis suppurativa

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

Clinical criteria:

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR
- Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 16 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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

(1) two completed authority prescription forms; and

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

(i) the Hurley stage grading; and

(ii) the AN count; and

(iii) the name of the antibiotic/s received for two separate courses each of three months; or

(iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics.

The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics.

Two completed authority prescriptions should be submitted with every initial application for this drug.

One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats.

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

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 2 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**

- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 16 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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

(1) two completed authority prescription forms; and

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

(i) the Hurley stage grading; and

(ii) the AN count.

Two completed authority prescriptions should be submitted with every initial application for this drug.

One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 16 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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

(1) two completed authority prescription forms; and

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

(i) the Hurley stage grading; and

(ii) the AN count.

Two completed authority prescriptions should be submitted with every initial application for this drug.

One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

secukinumab 150 mg/mL injection, 2 x 1 mL pen devices

14161H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1404.60	31.60	Cosentyx [NV]

▪ SECUKINUMAB

Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab prior to 1 June 2024 is considered to start their first cycle as of 1 June 2024.

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

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

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

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

(2) Grandfather patients (secukinumab only).

A patient who commenced treatment with secukinumab for moderate to severe hidradenitis suppurativa prior to 1 June 2024 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this restriction. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing/swapping therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response as defined in the restriction within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

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

Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

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

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

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

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

Note Special Pricing Arrangements apply.

Authority required

Moderate to severe hidradenitis suppurativa

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

Clinical criteria:

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR
- Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 16 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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

(1) two completed authority prescription forms; and

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

(i) the Hurley stage grading; and

(ii) the AN count; and

(iii) the name of the antibiotic/s received for two separate courses each of three months; or

(iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics.

The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics.

This restriction is intended for induction dosing only.

Two completed authority prescriptions should be submitted with every initial application for this drug.

One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats.

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

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 2 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 16 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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

(1) two completed authority prescription forms; and

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

(i) the Hurley stage grading; and

(ii) the AN count.

Two completed authority prescriptions should be submitted with every initial application for this drug.

One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats.

This restriction is intended for induction dosing only.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 16 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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

(1) two completed authority prescription forms; and

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

(i) the Hurley stage grading; and

(ii) the AN count.

Two completed authority prescriptions should be submitted with every initial application for this drug.

One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats.

This restriction is intended for induction dosing only.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

secukinumab 150 mg/mL injection, 2 x 1 mL pen devices

14154Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	..	..	*5428.41	31.60	Cosentyx [NV]

▪ SEMAGLUTIDE

Note Special Pricing Arrangements apply.

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

Note Where an SGLT2 inhibitor is being accessed through a PBS indication other than diabetes, the clinical criterion excluding concomitant treatment with an SGLT2 inhibitor is in relation to diabetes mellitus type 2 only.

Authority required (STREAMLINED)

15263

Diabetes mellitus type 2

Treatment Phase: Subsequent PBS-prescriptions for any GLP-1 receptor agonist

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment for type 2 diabetes mellitus with any of: an SGLT2 inhibitor, a DPP4 inhibitor, another GLP-1 receptor agonist.

semaglutide 1.34 mg/mL injection, 1 x 1.5 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14149Q NP	‡1	5	..	133.80	31.60	Ozempic [NO]

semaglutide 1.34 mg/mL injection, 1 x 3 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14163K NP	‡1	5	..	133.80	31.60	Ozempic [NO]

▪ SEMAGLUTIDE

Note Special Pricing Arrangements apply.

Note Definition:

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

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

Note Where an SGLT2 inhibitor is being accessed through a PBS indication other than diabetes, the clinical criterion excluding concomitant treatment with an SGLT2 inhibitor is in relation to diabetes mellitus type 2 only.

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

Diabetes mellitus type 2

Treatment Phase: First PBS-prescription for this drug

Clinical criteria:

- The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin, **AND**
- The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin, **AND**
- Patient must not have achieved a clinically meaningful glycaemic response with an SGLT2 inhibitor; OR
- Patient must have a contraindication/intolerance requiring treatment discontinuation of an SGLT2 inhibitor.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment for type 2 diabetes mellitus with any of: an SGLT2 inhibitor, a DPP4 inhibitor, another GLP-1 receptor agonist.

semaglutide 1.34 mg/mL injection, 1 x 1.5 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12080T NP	‡1	5	..	133.80	31.60	Ozempic [NO]

semaglutide 1.34 mg/mL injection, 1 x 3 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12075M NP	‡1	5	..	133.80	31.60	Ozempic [NO]

▪ SITAGLIPTIN

Note Definition:

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

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

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)

15261

Diabetes mellitus type 2

Clinical criteria:

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

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

sitagliptin 100 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9182G NP	1	5	..	37.64	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

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9180E NP	1	5	..	37.64	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

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9181F NP	1	5	..	37.64	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

Note Definition:

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

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')
DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

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)

15287

Diabetes mellitus type 2

Clinical criteria:

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

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

sitagliptin 100 mg tablet, 28

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*62.29	31.60	[a] Januvia [XW]	[a] Sitagliptin Lupin [GQ]

13871C NP						[a] Sitagliptin Sandoz Pharma [SZ] [a] Sitaglo [CR]	[a] Sitagliptin SUN [RA] [a] Xelevia [XT]

sitagliptin 25 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
14021Y NP	2	5	..	*62.29	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

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
14058X NP	2	5	..	*62.29	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 Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),

(b) Red cell transfusion within the previous 3 months.

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

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

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)

15276

Diabetes mellitus type 2

Clinical criteria:

- The condition must be inadequately responsive to metformin.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

sitagliptin 100 mg + metformin hydrochloride 1 g tablet: modified release, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10089B NP	1	5	..	44.69	31.60	[a] Janumet XR [XW]	[a] Sitagliptin/Metformin Sandoz XR [SZ]

sitagliptin 50 mg + metformin hydrochloride 1 g tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9451K NP	1	5	..	39.79	31.60	[a] Janumet [XW] [a] Sitagliptin/Metformin Sandoz [SZ]	[a] SITAGLIPTIN/METFORMIN 50/1000 SUN [RA] [a] Velmetia [XT]

sitagliptin 50 mg + metformin hydrochloride 500 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9449H NP	1	5	..	38.75	31.60	[a] Janumet [XW] [a] Sitagliptin/Metformin Sandoz [SZ]	[a] SITAGLIPTIN/METFORMIN 50/500 SUN [RA] [a] Velmetia [XT]

sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9450J NP	1	5	..	39.49	31.60	[a] Janumet [XW] [a] Sitagliptin/Metformin Sandoz [SZ]	[a] SITAGLIPTIN/METFORMIN 50/850 SUN [RA] [a] Velmetia [XT]

sitagliptin 50 mg + metformin hydrochloride 1 g modified release tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10090C NP	1	5	..	45.75	31.60	[a] Janumet XR [XW]	[a] Sitagliptin/Metformin Sandoz XR [SZ]

▪ SITAGLIPTIN + METFORMIN

Note Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),

(b) Red cell transfusion within the previous 3 months.

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

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

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)

15288

Diabetes mellitus type 2

Clinical criteria:

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

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

sitagliptin 100 mg + metformin hydrochloride 1 g tablet: modified release, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
14031L 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

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
14035Q NP	2	5	..	*66.59	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

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13994M NP	2	5	..	*64.51	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

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
14064F NP	2	5	..	*65.99	31.60	[a] Janumet [XW]	[a] SITAGLIPTIN/METFORMIN 50/850 SUN [RA]
						[a] Sitagliptin/Metformin Sandoz [SZ]	[a] Velmetia [XT]

sitagliptin 50 mg + metformin hydrochloride 1 g modified release tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
13990H NP	2	5	..	*78.51	31.60	[a] Janumet XR [XW]	[a] Sitagliptin/Metformin Sandoz XR [SZ]

▪ TAFAMIDIS

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

Transthyretin amyloid cardiomyopathy

Treatment Phase: First PBS-subsidised prescription for this drug

Clinical criteria:

- The treatment must be for wild-type transthyretin-mediated amyloid cardiomyopathy, with documented evidence of transthyretin precursor protein present; OR
- The treatment must be for variant transthyretin-mediated (also known as hereditary transthyretin-mediated) amyloid cardiomyopathy, with documented evidence of transthyretin precursor protein present, **AND**
- Patient must have experienced at least one episode of hospitalisation that was a direct result of heart failure; OR
- Patient must have clinical evidence of heart failure without hospitalisation that required treatment with a diuretic for improvement, **AND**
- Patient must have/have had New York Heart Association class I heart failure at the time of commencing this drug; OR
- Patient must have/have had New York Heart Association class II heart failure at the time of commencing this drug, **AND**
- Patient must have an end-diastolic interventricular septal wall thickness of at least 12 mm on imaging, **AND**
- Patient must have an estimated glomerular filtration rate (eGFR) greater than 25 mL/minute/1.73 m^2.

Treatment criteria:

- Must be treated by a medical practitioner who is any of the following: (i) a cardiologist, (ii) a consultant physician with experience in the management of amyloid disorders; this authority application must be sought by the same medical practitioner providing treatment.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

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

(a) a completed authority prescription form; and

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

Evidence of clinical findings to establish the diagnosis:

In this authority application, confirm that there is documented evidence of transthyretin precursor protein through either (1) alone, or, both (2) and (3), from the list below:

Confirm the following has been completed:

(1) amyloid expert centre histology findings derived via immunohistochemistry or mass spectrometry; OR

(2) bone scintigraphy with grade 2-3 finding AND

(3) Confirm that there are negative results for monoclonal protein on each of the following three tests:

(a) serum immunofixation (also known as protein electrophoresis)

(b) urine immunofixation

(c) serum free light chains blood test

State which of (1) to (3) above has been completed, as well as the:

(i) date of the finding,

(ii) imaging/pathology report number/code that links the finding to the patient,

(iii) name of the amyloid expert centre in this authority application.

For end-diastolic interventricular septal wall thickness (at least 12 mm), confirm that:

(i) imaging (echocardiogram or magnetic resonance imaging) has been undertaken; and

(ii) that the imaging report is stored in the patient's medical records.

State the date that the imaging was performed and the thickness (in mm) in this authority application.

Where this authority application is to transition a patient from non-PBS-subsidised to PBS-subsidised supply (i.e. a 'grandfathered' patient), confirm the following:

(i) the patient's heart failure has not worsened to persistent New York Heart Association Class III/IV heart failure while taking this drug.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note The Australian Amyloid Network provides a list of clinic centres that manage amyloidosis. It also provides a list of Australian anatomical pathology laboratories to be contacted for tissue review and immunohistochemistry for amyloid typing. For the purposes of this restriction, these providers are considered to be amyloid expert centres.

Authority required

Transthyretin amyloid cardiomyopathy

Treatment Phase: Second and subsequent PBS-subsidised prescriptions for this drug

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have an estimated glomerular filtration rate (eGFR) greater than 25 mL/minute/1.73 m^2, **AND**

- The treatment must be ceased where the patient's heart failure has worsened to persistent New York Heart Association (NYHA) Class III/IV heart failure, **AND**
- The treatment must be ceased where the patient has received any of: (i) a heart transplant, (ii) a liver transplant, (iii) an implanted ventricular assist device.

Treatment criteria:

- Must be treated by a medical practitioner who is any of the following: (i) a cardiologist, (ii) a consultant physician with experience in the management of amyloid disorders; this authority application must be sought by the same medical practitioner providing treatment.

Confirm whether heart failure has worsened to NYHA Class III/IV since the last authority application (yes/no).

If 'no', continued PBS subsidy is available.

If 'yes', continued PBS subsidy is available, but the prescriber must undertake a review of the patient within 3 months to determine whether the worsening heart failure was transient or persistent.

Where this subsequent clinical review finds that the heart failure persists as NYHA Class III/IV heart failure despite active treatment with this drug, then PBS subsidy is not available.

If heart failure has worsened to NYHA Class III/IV since the last authority application, no more than 2 repeat prescriptions must be prescribed.

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

tafamidis 61 mg capsule, 30

14100D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	10022.13	31.60	Vyndamax [PF]

▪ VILDAGLIPTIN

Note Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),

(b) Red cell transfusion within the previous 3 months.

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

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')

GLP-1 - glucagon-like peptide-1 receptor agonist

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)

15261

Diabetes mellitus type 2

Clinical criteria:

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

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

vildagliptin 50 mg tablet, 60

3415R

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	50.12	31.60	Galvus [NV]

▪ VILDAGLIPTIN

Note Definition:

A HbA1c measurement greater than 7% despite treatment with the specified prior therapy/therapies indicates inadequate responsiveness. Where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2-week period indicates inadequate responsiveness.

Blood glucose monitoring is an alternative to HbA1c measurement where at least one of the following circumstances applies:

(a) A clinical condition with reduced red blood cell survival (inclusive of haemolytic anaemias, haemoglobinopathies),

(b) Red cell transfusion within the previous 3 months.

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

Note Abbreviations used in the restriction are as follows:

SGLT2 - sodium glucose transporter-2 inhibitor (drug names ending in 'flozin')

DPP4 - dipeptidyl peptidase-4 inhibitor (drug names ending in 'gliptin')
GLP-1 - glucagon-like peptide-1 receptor agonist

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)

15287

Diabetes mellitus type 2

Clinical criteria:

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

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

vildagliptin 50 mg tablet, 60

13846R NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*87.25	31.60	Galvus [NV]

▪ VILDAGLIPTIN + METFORMIN

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

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

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)

15276

Diabetes mellitus type 2

Clinical criteria:

- The condition must be inadequately responsive to metformin.

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

vildagliptin 50 mg + metformin hydrochloride 1 g tablet, 60

5476F NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	51.51	31.60	Galvumet 50/1000 [NV]

vildagliptin 50 mg + metformin hydrochloride 500 mg tablet, 60

5474D NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	50.20	31.60	Galvumet 50/500 [NV]

vildagliptin 50 mg + metformin hydrochloride 850 mg tablet, 60

5475E NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	51.05	31.60	Galvumet 50/850 [NV]

▪ VILDAGLIPTIN + METFORMIN

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

(b) Red cell transfusion within the previous 3 months.
Document HbA1c measurements (blood glucose measurements where relevant), as well as any intolerances/contraindications in the patient's medical records.

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

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)

15288

Diabetes mellitus type 2

Clinical criteria:

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

Treatment criteria:

- Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.

vildagliptin 50 mg + metformin hydrochloride 1 g tablet, 60

14032M NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*90.03	31.60	Galvumet 50/1000 [NV]

vildagliptin 50 mg + metformin hydrochloride 500 mg tablet, 60

13877J NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*87.41	31.60	Galvumet 50/500 [NV]

vildagliptin 50 mg + metformin hydrochloride 850 mg tablet, 60

13991J NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*89.11	31.60	Galvumet 50/850 [NV]

Highly Specialised Drugs Program (Private Hospital)

▪ CICLOSPORIN

Caution Careful monitoring of patients is mandatory.

Authority required (STREAMLINED)

9764

Management of transplant rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must have had an organ or tissue transplantation, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Authority required (STREAMLINED)

9695

Severe atopic dermatitis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Treatment criteria:

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist.

Clinical criteria:

- The condition must be ineffective to other systemic therapies; OR
- The condition must be inappropriate for other systemic therapies.

Authority required (STREAMLINED)

15300

Severe psoriasis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- The condition must be ineffective to other systemic therapies; OR
- The condition must be inappropriate for other systemic therapies, **AND**
- The condition must have caused significant interference with quality of life.

Treatment criteria:

- Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) a rheumatologist, (iii) general physician; OR
- Must be treated by a medical practitioner in consultation with one of the above specialist types who is either an accredited: (i) dermatology registrar, (ii) rheumatology registrar.

For patients who do not demonstrate an adequate response to apremilast, a Psoriasis Area and Severity Index (PASI) assessment must be completed, preferably while on treatment, but no longer than 4 weeks following the cessation of treatment. This assessment will be required for patients who transition to 'biological medicines' for the treatment of 'severe chronic plaque psoriasis'.

This assessment must be documented in the patient's medical records.

Authority required (STREAMLINED)

9694

Nephrotic syndrome

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must have failed prior treatment with steroids and cytostatic drugs; OR
- Patient must be intolerant to treatment with steroids and cytostatic drugs; OR
- The condition must be considered inappropriate for treatment with steroids and cytostatic drugs, **AND**
- Patient must not have renal impairment.

Treatment criteria:

- Must be treated by a nephrologist.

Authority required (STREAMLINED)

9742

Severe active rheumatoid arthritis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- The condition must have been ineffective to prior treatment with classical slow-acting anti-rheumatic agents (including methotrexate); OR
- The condition must be considered inappropriate for treatment with slow-acting anti-rheumatic agents (including methotrexate).

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist.

ciclosporin 10 mg capsule, 60

6232B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	..	*86.77	Neoral 10 [NV]

ciclosporin 100 mg capsule, 30

6354K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
4	5	..	*397.13	[a] APO-Ciclosporin [TX] [a] Neoral 100 [NV]	[a] Cyclosporin Sandoz [NM]

ciclosporin 25 mg capsule, 30

6352H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
4	5	..	*100.53	[a] APO-Ciclosporin [TX] [a] Neoral 25 [NV]	[a] Cyclosporin Sandoz [NM]

ciclosporin 50 mg capsule, 30

6353J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
4	5	..	*199.17	[a] APO-Ciclosporin [TX] [a] Neoral 50 [NV]	[a] Cyclosporin Sandoz [NM]

ciclosporin 100 mg/mL oral liquid, 50 mL

6125J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
4	5	..	*1311.53	Neoral [NV]

▪ IVACAFTOR

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

Note Special Pricing Arrangements apply.

Authority required

Cystic fibrosis

Treatment Phase: Initial treatment - New patient (non-gating mutations)

Clinical criteria:

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have at least one mutation in the CFTR gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data, **AND**
- Patient must not have either: (i) G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene; (ii) other gating (class III) mutation in the CFTR gene, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged 4 months or older.

For the purposes of this restriction, the list of mutations considered to be responsive to ivacaftor is defined in the TGA approved Product Information.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem,

erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

(1) a completed authority prescription; and

(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and

(3) details of the pathology report substantiating the specific mutation considered to be responsive to ivacaftor as listed in the TGA approved Product Information. Quote each of the: (i) the specific mutation listed in the TGA approved Product Information, (ii) name of the pathology report provider, (iii) date of pathology report, (iv) unique identifying number/code that links the pathology result to the individual patient, and

(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

Authority required

Cystic fibrosis

Treatment Phase: Continuing treatment (non-gating mutations)

Clinical criteria:

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged 4 months or older.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

(1) a completed authority prescription; and

(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and

(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

ivacaftor 25 mg granules, 56 sachets

14147N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	21423.37	Kalydeco [VR]

ivacaftor 50 mg granules, 56 sachets

14158E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	21423.37	Kalydeco [VR]

ivacaftor 75 mg granules, 56 sachets

14157D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	21423.37	Kalydeco [VR]

ivacaftor 150 mg tablet, 56

14169R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	21423.37	Kalydeco [VR]

▪ IVACAFTOR

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

Note Special Pricing Arrangements apply.

Authority required

Cystic fibrosis

Treatment Phase: Initial treatment - New patient (gating mutations)

Clinical criteria:

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR
- Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged 4 months or older.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

(1) a completed authority prescription; and

(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and

(3) details of the pathology report substantiating G551D mutation or other gating (Class III) mutation on the CFTR gene - quote each of the: (i) the specific CFTR mutation listed in the TGA approved Product Information, (ii) name of the pathology report provider, (iii) date of pathology report, (iv) unique identifying number/code that links the pathology result to the individual patient, and

(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

Note For the purposes of this restriction, the list of gating mutations are: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N or S549R.

Authority required

Cystic fibrosis

Treatment Phase: Continuing treatment (gating mutations)

Clinical criteria:

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged 4 months or older.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

(1) a completed authority prescription; and

(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and

(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

ivacaftor 25 mg granules, 56 sachets

14165M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	..	21423.37	Kalydeco [VR]

ivacaftor 50 mg granules, 56 sachets

11097C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	..	21423.37	Kalydeco [VR]

ivacaftor 75 mg granules, 56 sachets

11109Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	..	21423.37	Kalydeco [VR]

ivacaftor 150 mg tablet, 56

10175M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	..	21423.37	Kalydeco [VR]

▪ RIOCIGUAT

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 1 month following cessation of therapy, as recommended by the TGA-approved Product Information.

Note Special Pricing Arrangements apply.

Authority required

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have WHO Functional Class II, III or IV CTEPH, **AND**
- The condition must be inoperable by pulmonary endarterectomy; OR
- The condition must be recurrent or persistent following pulmonary endarterectomy, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated in a centre with expertise in the management of CTEPH.

Population criteria:

- Patient must be at least 18 years of age.

CTEPH that is inoperable by pulmonary endarterectomy is defined as follows:

(a) Right heart catheterisation (RHC) demonstrating pulmonary vascular resistance (PVR) of greater than 300 dyn*sec*cm^{-5} measured at least 90 days after start of full anticoagulation; and

(b) A mean pulmonary artery pressure (PAPmean) of greater than 25 mmHg at least 90 days after start of full anticoagulation.

CTEPH that is recurrent or persistent subsequent to pulmonary endarterectomy is defined as follows:

RHC demonstrating a PVR of greater than 300 dyn*sec*cm^{-5} measured at least 180 days following pulmonary endarterectomy.

Where a RHC cannot be performed due to right ventricular dysfunction, an echocardiogram demonstrating the dysfunction must be documented in the patient's medical records.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

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

(a) a completed authority prescription form; and

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

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

(a) the results from the 3 tests below, to establish baseline measurements, where available:

(i) RHC composite assessment, and

(ii) ECHO composite assessment, and

(iii) 6 Minute Walk Test (6MWT); and

(b) confirmation of evidence of inoperable CTEPH including the pulmonary vascular resistance (PVR) value, a mean pulmonary artery pressure (PAPmean) and the starting date of full anticoagulation; or

(c) confirmation of evidence of recurrent or persistent CTEPH including the PVR value and the date that pulmonary endarterectomy was performed; or

(d) confirmation of an echocardiogram demonstrating right ventricular dysfunction.

Where it is not possible to perform all 3 tests above on clinical grounds, the expected test combination, in descending order of preference is:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstance where a RHC cannot be performed on clinical grounds, the expected test combinations, in descending order of preference is:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be documented in the patient's medical records.

The test results provided must not be more than 2 months old at the time of application.

Prescriptions for dose titration must provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, The quantity approved must be based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 3 repeats.

The assessment of the patient's response to the initial 20-week course of treatment should be made following the preceding 16 weeks of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must demonstrate stable or responding disease, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated in a centre with expertise in the management of CTEPH.

Population criteria:

- Patient must be at least 18 years of age.

Response to this drug is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease.

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be documented in the patient's medical record with each continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be documented in the patient's medical records.

The test results conducted for continuing treatment must be no more than 2 months old at the time of application.

The assessment of the patient's response to the continuing 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

The maximum quantity per prescription must be based on the dosage recommendations in the TGA-approved Product Information and be limited to provide sufficient supply for 1 month of treatment.

A maximum of 5 repeats will be authorised.

Patients who fail to demonstrate disease stability or improvement to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

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

Authority required

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete a maximum of 20 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete a maximum of 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 20 or 24 weeks of treatment available under the above respective restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated in a centre with expertise in the management of CTEPH.

Population criteria:

- Patient must be at least 18 years of age.

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

riociguat 500 microgram tablet, 42

11009K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	1680.19	Adempas [BN]

riociguat 1 mg tablet, 42

10990K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	1680.19	Adempas [BN]

riociguat 1.5 mg tablet, 42

10974N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	1680.19	Adempas [BN]

riociguat 2 mg tablet, 42

11012N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	1680.19	Adempas [BN]

riociguat 2.5 mg tablet, 42

10985E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	1680.19	Adempas [BN]

Highly Specialised Drugs Program (Public Hospital)

▪ CICLOSPORIN

Caution Careful monitoring of patients is mandatory.

Authority required (STREAMLINED)

6643

Management of transplant rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must have had an organ or tissue transplantation, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Authority required (STREAMLINED)

6660

Severe atopic dermatitis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Treatment criteria:

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist.

Clinical criteria:

- The condition must be ineffective to other systemic therapies; OR
- The condition must be inappropriate for other systemic therapies.

Authority required (STREAMLINED)

15259

Severe psoriasis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- The condition must be ineffective to other systemic therapies; OR
- The condition must be inappropriate for other systemic therapies, **AND**
- The condition must have caused significant interference with quality of life.

Treatment criteria:

- Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) a rheumatologist, (iii) general physician; OR
- Must be treated by a medical practitioner in consultation with one of the above specialist types who is either an accredited: (i) dermatology registrar, (ii) rheumatology registrar.

For patients who do not demonstrate an adequate response to apremilast, a Psoriasis Area and Severity Index (PASI) assessment must be completed, preferably while on treatment, but no longer than 4 weeks following the cessation of treatment. This assessment will be required for patients who transition to 'biological medicines' for the treatment of 'severe chronic plaque psoriasis'.

This assessment must be documented in the patient's medical records.

Authority required (STREAMLINED)

6631

Nephrotic syndrome

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must have failed prior treatment with steroids and cytostatic drugs; OR
- Patient must be intolerant to treatment with steroids and cytostatic drugs; OR
- The condition must be considered inappropriate for treatment with steroids and cytostatic drugs, **AND**
- Patient must not have renal impairment.

Treatment criteria:

- Must be treated by a nephrologist.

Authority required (STREAMLINED)

6638

Severe active rheumatoid arthritis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- The condition must have been ineffective to prior treatment with classical slow-acting anti-rheumatic agents (including methotrexate); OR
- The condition must be considered inappropriate for treatment with slow-acting anti-rheumatic agents (including methotrexate).

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist.

ciclosporin 10 mg capsule, 60

5632K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	..	*74.40	Neoral 10 [NV]

ciclosporin 100 mg capsule, 30

5636P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
4	5	..	*373.80	[a] APO-Ciclosporin [TX] [a] Neoral 100 [NV]	[a] Cyclosporin Sandoz [NM]

ciclosporin 25 mg capsule, 30

5634M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
4	5	..	*88.16	[a] APO-Ciclosporin [TX] [a] Neoral 25 [NV]	[a] Cyclosporin Sandoz [NM]

ciclosporin 50 mg capsule, 30

5635N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
4	5	..	*183.48	[a] APO-Ciclosporin [TX] [a] Neoral 50 [NV]	[a] Cyclosporin Sandoz [NM]

ciclosporin 100 mg/mL oral liquid, 50 mL

5633L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
4	5	..	*1263.16	Neoral [NV]

▪ IVACAFTOR

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

Note Special Pricing Arrangements apply.

Authority required

Cystic fibrosis

Treatment Phase: Initial treatment - New patient (non-gating mutations)

Clinical criteria:

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have at least one mutation in the CFTR gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data, **AND**
- Patient must not have either: (i) G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene; (ii) other gating (class III) mutation in the CFTR gene, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged 4 months or older.

For the purposes of this restriction, the list of mutations considered to be responsive to ivacaftor is defined in the TGA approved Product Information.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem,

erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

(1) a completed authority prescription; and

(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and

(3) details of the pathology report substantiating the specific mutation considered to be responsive to ivacaftor as listed in the TGA approved Product Information. Quote each of the: (i) the specific mutation listed in the TGA approved Product Information, (ii) name of the pathology report provider, (iii) date of pathology report, (iv) unique identifying number/code that links the pathology result to the individual patient, and

(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

Authority required

Cystic fibrosis

Treatment Phase: Continuing treatment (non-gating mutations)

Clinical criteria:

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged 4 months or older.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

(1) a completed authority prescription; and

(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and

(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

ivacaftor 25 mg granules, 56 sachets

14155B

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

ivacaftor 50 mg granules, 56 sachets

14148P

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

ivacaftor 75 mg granules, 56 sachets

14167P

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

ivacaftor 150 mg tablet, 56

14153X

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

▪ IVACAFTOR

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

Note Special Pricing Arrangements apply.

Authority required

Cystic fibrosis

Treatment Phase: Initial treatment - New patient (gating mutations)

Clinical criteria:

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR
- Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged 4 months or older.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

(1) a completed authority prescription; and

(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and

(3) details of the pathology report substantiating G551D mutation or other gating (Class III) mutation on the CFTR gene - quote each of the: (i) the specific CFTR mutation listed in the TGA approved Product Information, (ii) name of the pathology report provider, (iii) date of pathology report, (iv) unique identifying number/code that links the pathology result to the individual patient, and

(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

Note For the purposes of this restriction, the list of gating mutations are: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N or S549R.

Authority required

Cystic fibrosis

Treatment Phase: Continuing treatment (gating mutations)

Clinical criteria:

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged 4 months or older.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

(1) a completed authority prescription; and

(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and

(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

ivacaftor 25 mg granules, 56 sachets

14156C

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

ivacaftor 50 mg granules, 56 sachets

11105L

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

ivacaftor 75 mg granules, 56 sachets

11098D

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

ivacaftor 150 mg tablet, 56

10170G

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

▪ RIOCIGUAT

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 1 month following cessation of therapy, as recommended by the TGA-approved Product Information.

Note Special Pricing Arrangements apply.

Authority required

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have WHO Functional Class II, III or IV CTEPH, **AND**
- The condition must be inoperable by pulmonary endarterectomy; OR
- The condition must be recurrent or persistent following pulmonary endarterectomy, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated in a centre with expertise in the management of CTEPH.

Population criteria:

- Patient must be at least 18 years of age.

CTEPH that is inoperable by pulmonary endarterectomy is defined as follows:

(a) Right heart catheterisation (RHC) demonstrating pulmonary vascular resistance (PVR) of greater than 300 dyn*sec*cm^{-5} measured at least 90 days after start of full anticoagulation; and

(b) A mean pulmonary artery pressure (PAPmean) of greater than 25 mmHg at least 90 days after start of full anticoagulation.

CTEPH that is recurrent or persistent subsequent to pulmonary endarterectomy is defined as follows:

RHC demonstrating a PVR of greater than 300 dyn*sec*cm^{-5} measured at least 180 days following pulmonary endarterectomy.

Where a RHC cannot be performed due to right ventricular dysfunction, an echocardiogram demonstrating the dysfunction must be documented in the patient's medical records.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

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

(a) a completed authority prescription form; and

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

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

(a) the results from the 3 tests below, to establish baseline measurements, where available:

(i) RHC composite assessment, and

(ii) ECHO composite assessment, and

(iii) 6 Minute Walk Test (6MWT); and

(b) confirmation of evidence of inoperable CTEPH including the pulmonary vascular resistance (PVR) value, a mean pulmonary artery pressure (PAPmean) and the starting date of full anticoagulation; or

(c) confirmation of evidence of recurrent or persistent CTEPH including the PVR value and the date that pulmonary endarterectomy was performed; or

(d) confirmation of an echocardiogram demonstrating right ventricular dysfunction.

Where it is not possible to perform all 3 tests above on clinical grounds, the expected test combination, in descending order of preference is:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstance where a RHC cannot be performed on clinical grounds, the expected test combinations, in descending order of preference is:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be documented in the patient's medical records.

The test results provided must not be more than 2 months old at the time of application.

Prescriptions for dose titration must provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, The quantity approved must be based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 3 repeats.

The assessment of the patient's response to the initial 20-week course of treatment should be made following the preceding 16 weeks of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must demonstrate stable or responding disease, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated in a centre with expertise in the management of CTEPH.

Population criteria:

- Patient must be at least 18 years of age.

Response to this drug is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease.

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be documented in the patient's medical record with each continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be documented in the patient's medical records.

The test results conducted for continuing treatment must be no more than 2 months old at the time of application.

The assessment of the patient's response to the continuing 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

The maximum quantity per prescription must be based on the dosage recommendations in the TGA-approved Product Information and be limited to provide sufficient supply for 1 month of treatment.

A maximum of 5 repeats will be authorised.

Patients who fail to demonstrate disease stability or improvement to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

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

Authority required

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete a maximum of 20 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete a maximum of 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 20 or 24 weeks of treatment available under the above respective restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated in a centre with expertise in the management of CTEPH.

Population criteria:

- Patient must be at least 18 years of age.

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

riociguat 500 microgram tablet, 42

11001B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	1631.82	Adempas [BN]

riociguat 1 mg tablet, 42

10976Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	1631.82	Adempas [BN]

riociguat 1.5 mg tablet, 42

10989J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	1631.82	Adempas [BN]

riociguat 2 mg tablet, 42

10984D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	1631.82	Adempas [BN]

riociguat 2.5 mg tablet, 42

11002C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	1631.82	Adempas [BN]