



Australian Government

Department of Health



Schedule of Pharmaceutical Benefits

Summary of Changes

Effective 1 July 2019



Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 July 2019 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	\$7.39
	Dangerous drug fee	\$3.11
	Extemporaneously-prepared	\$9.43
	Allowable additional patient charge*	\$4.53
Additional Fees (for safety net prices):	Ready-prepared	\$1.25
	Extemporaneously-prepared	\$1.61
Patient Co-payments:	General	\$40.30
	Concessional	\$6.50
Safety Net Thresholds:	General	\$1550.70
	Concessional	\$390.00
Safety Net Card Issue Fee:		\$10.10

* 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 July 2019. The Schedule is updated on the first day of each month and is available on the internet at www.pbs.gov.au.

General Pharmaceutical Benefits

Additions

Addition – Item

- 11716P **ISOTRETINOIN**, isotretinoin 5 mg capsule, 60 (*Oratane*)
11713L **PHENELZINE**, phenelzine 15 mg tablet, 60 (*Nardil*)

Addition – Brand

- 8439E *Celecoxib BTC, JB* – **CELECOXIB**, celecoxib 100 mg capsule, 60
8439E *GenRx Celecoxib, GX* – **CELECOXIB**, celecoxib 100 mg capsule, 60
8440F *Celecoxib BTC, JB* – **CELECOXIB**, celecoxib 200 mg capsule, 30
8440F *GenRx Celecoxib, GX* – **CELECOXIB**, celecoxib 200 mg capsule, 30
9022W *Fenofibrate Mylan, AF* – **FENOFIBRATE**, fenofibrate 48 mg tablet, 60
9246P *Fenofibrate Mylan, AF* – **FENOFIBRATE**, fenofibrate 48 mg tablet, 60
9023X *Fenofibrate Mylan, AF* – **FENOFIBRATE**, fenofibrate 145 mg tablet, 30
9247Q *Fenofibrate Mylan, AF* – **FENOFIBRATE**, fenofibrate 145 mg tablet, 30
1558B *APO-Isosorbide Mononitrate, TX* – **ISOSORBIDE MONONITRATE**, isosorbide mononitrate 60 mg modified release tablet, 30
8627C *Montelukast APOTEX, GX* – **MONTELUKAST**, montelukast 4 mg chewable tablet, 28
8628D *Montelukast APOTEX, GX* – **MONTELUKAST**, montelukast 5 mg chewable tablet, 28
5292M *Olmesartan/Amlodipine 20/5 APOTEX, TX* – **OLMESARTAN MEDOXOMIL + AMLODIPINE**, olmesartan medoxomil 20 mg + amlodipine 5 mg tablet, 30
5293N *Olmesartan/Amlodipine 40/5 APOTEX, TX* – **OLMESARTAN MEDOXOMIL + AMLODIPINE**, olmesartan medoxomil 40 mg + amlodipine 5 mg tablet, 30
5294P *Olmesartan/Amlodipine 40/10 APOTEX, TX* – **OLMESARTAN MEDOXOMIL + AMLODIPINE**, olmesartan medoxomil 40 mg + amlodipine 10 mg tablet, 30
8363E *Raloxifene GH, GQ* – **RALOXIFENE**, raloxifene hydrochloride 60 mg tablet, 28
8378Y *Temozolomide Juno, JX* – **TEMOZOLOMIDE**, temozolomide 5 mg capsule, 5
8819E *Temozolomide Juno, JX* – **TEMOZOLOMIDE**, temozolomide 5 mg capsule, 5
8379B *Temozolomide Juno, JX* – **TEMOZOLOMIDE**, temozolomide 20 mg capsule, 5
8820F *Temozolomide Juno, JX* – **TEMOZOLOMIDE**, temozolomide 20 mg capsule, 5
8380C *Temozolomide Juno, JX* – **TEMOZOLOMIDE**, temozolomide 100 mg capsule, 5
8821G *Temozolomide Juno, JX* – **TEMOZOLOMIDE**, temozolomide 100 mg capsule, 5
9361Q *Temozolomide Juno, JX* – **TEMOZOLOMIDE**, temozolomide 140 mg capsule, 5
9362R *Temozolomide Juno, JX* – **TEMOZOLOMIDE**, temozolomide 140 mg capsule, 5
10062N *Temozolomide Juno, JX* – **TEMOZOLOMIDE**, temozolomide 180 mg capsule, 5

2438H	<i>Temozolomide Juno, JX</i> – TEMOZOLOMIDE , temozolomide 180 mg capsule, 5
8381D	<i>Temozolomide Juno, JX</i> – TEMOZOLOMIDE , temozolomide 250 mg capsule, 5
8350L	<i>Tirofiban Juno, JU</i> – TIROFIBAN , tirofiban 12.5 mg/50 mL injection, 50 mL vial
9070J	<i>Ziprasidone GH, GQ</i> – ZIPRASIDONE , ziprasidone 20 mg capsule, 60
9071K	<i>Ziprasidone GH, GQ</i> – ZIPRASIDONE , ziprasidone 40 mg capsule, 60
9072L	<i>Ziprasidone GH, GQ</i> – ZIPRASIDONE , ziprasidone 60 mg capsule, 60
9073M	<i>Ziprasidone GH, GQ</i> – ZIPRASIDONE , ziprasidone 80 mg capsule, 60

Addition – Equivalence Indicator

2856H	<i>Nardil, LM</i> – PHENELZINE , phenelzine 15 mg tablet, 100
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Deletions

Deletion – Item

8048N	ABCIXIMAB , abciximab 10 mg/5 mL injection, 5 mL vial (<i>ReoPro</i>)
2738D	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE , amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 500 g (<i>XP Maxamaid</i>)
9164H	CYSTINE WITH CARBOHYDRATE , cystine with carbohydrate containing 500 mg cystine oral liquid: powder for, 30 x 4 g sachets (<i>Cystine 500</i>)
8726G	GLATIRAMER ACETATE , glatiramer acetate 20 mg/mL injection, 28 x 1 mL syringes (<i>Copaxone</i>)
1966L	PYRIMETHAMINE , pyrimethamine 25 mg tablet, 50 (<i>Daraprim</i>)
9060W	ROSIGLITAZONE + METFORMIN , rosiglitazone 2 mg + metformin hydrochloride 1 g tablet, 56 (<i>Avandamet</i>)
9059T	ROSIGLITAZONE + METFORMIN , rosiglitazone 2 mg + metformin hydrochloride 500 mg tablet, 56 (<i>Avandamet</i>)
9062Y	ROSIGLITAZONE + METFORMIN , rosiglitazone 4 mg + metformin hydrochloride 1 g tablet, 56 (<i>Avandamet</i>)
9061X	ROSIGLITAZONE + METFORMIN , rosiglitazone 4 mg + metformin hydrochloride 500 mg tablet, 56 (<i>Avandamet</i>)

Deletion – Brand

5006L	<i>Chem mart Amoxicillin and Clavulanic Acid, CH</i> – AMOXICILLIN + CLAVULANIC ACID , amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10
5006L	<i>Terry White Chemists Amoxicillin and Clavulanic Acid, TW</i> – AMOXICILLIN + CLAVULANIC ACID , amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10
8254K	<i>Chem mart Amoxicillin and Clavulanic Acid, CH</i> – AMOXICILLIN + CLAVULANIC ACID , amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10
8254K	<i>Terry White Chemists Amoxicillin and Clavulanic Acid, TW</i> – AMOXICILLIN + CLAVULANIC ACID , amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10
8213G	<i>Chem mart Atorvastatin, CH</i> – ATORVASTATIN , atorvastatin 10 mg tablet, 30
9230T	<i>Chem mart Atorvastatin, CH</i> – ATORVASTATIN , atorvastatin 10 mg tablet, 30
8214H	<i>Chem mart Atorvastatin, CH</i> – ATORVASTATIN , atorvastatin 20 mg tablet, 30
9231W	<i>Chem mart Atorvastatin, CH</i> – ATORVASTATIN , atorvastatin 20 mg tablet, 30
8215J	<i>Chem mart Atorvastatin, CH</i> – ATORVASTATIN , atorvastatin 40 mg tablet, 30
9232X	<i>Chem mart Atorvastatin, CH</i> – ATORVASTATIN , atorvastatin 40 mg tablet, 30
8521L	<i>Chem mart Atorvastatin, CH</i> – ATORVASTATIN , atorvastatin 80 mg tablet, 30
9233Y	<i>Chem mart Atorvastatin, CH</i> – ATORVASTATIN , atorvastatin 80 mg tablet, 30
8295N	<i>Chem mart Candesartan, CH</i> – CANDESARTAN , candesartan cilexetil 4 mg tablet, 30
8295N	<i>Terry White Chemists Candesartan, TW</i> – CANDESARTAN , candesartan cilexetil 4 mg tablet, 30
8296P	<i>Chem mart Candesartan, CH</i> – CANDESARTAN , candesartan cilexetil 8 mg tablet, 30
8296P	<i>Terry White Chemists Candesartan, TW</i> – CANDESARTAN , candesartan cilexetil 8 mg tablet, 30
8297Q	<i>Chem mart Candesartan, CH</i> – CANDESARTAN , candesartan cilexetil 16 mg tablet, 30
8297Q	<i>Terry White Chemists Candesartan, TW</i> – CANDESARTAN , candesartan cilexetil 16 mg tablet, 30
8889W	<i>Chem mart Candesartan, CH</i> – CANDESARTAN , candesartan cilexetil 32 mg tablet, 30
8889W	<i>Terry White Chemists Candesartan, TW</i> – CANDESARTAN , candesartan cilexetil 32 mg tablet, 30

8504N *Chem mart Candesartan HCTZ 16/12.5, CH* – **CANDESARTAN + HYDROCHLOROTHIAZIDE**, candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30

8504N *Terry White Chemists Candesartan HCTZ 16/12.5, TW* – **CANDESARTAN + HYDROCHLOROTHIAZIDE**, candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30

9314F *Chem mart Candesartan HCTZ 32/12.5, CH* – **CANDESARTAN + HYDROCHLOROTHIAZIDE**, candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30

9314F *Terry White Chemists Candesartan HCTZ 32/12.5, TW* – **CANDESARTAN + HYDROCHLOROTHIAZIDE**, candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30

9315G *Chem mart Candesartan HCTZ 32/25, CH* – **CANDESARTAN + HYDROCHLOROTHIAZIDE**, candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30

9315G *Terry White Chemists Candesartan HCTZ 32/25, TW* – **CANDESARTAN + HYDROCHLOROTHIAZIDE**, candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30

8318T *Chem mart Clarithromycin, CH* – **CLARITHROMYCIN**, clarithromycin 250 mg tablet, 14

8318T *Terry White Chemists Clarithromycin, TW* – **CLARITHROMYCIN**, clarithromycin 250 mg tablet, 14

9296G *Chem mart Clopidogrel/Aspirin 75/100, CH* – **CLOPIDOGREL + ASPIRIN**, clopidogrel 75 mg + aspirin 100 mg tablet, 30

9296G *Terry White Chemists Clopidogrel/Aspirin 75/100, TW* – **CLOPIDOGREL + ASPIRIN**, clopidogrel 75 mg + aspirin 100 mg tablet, 30

1204J *Flucon, NV* – **FLUOROMETHOLONE**, fluorometholone 0.1% eye drops, 5 mL

5513E *Flucon, NV* – **FLUOROMETHOLONE**, fluorometholone 0.1% eye drops, 5 mL

8532C *Chem mart Indapamide SR, CH* – **INDAPAMIDE**, indapamide hemihydrate 1.5 mg modified release tablet, 90

8532C *Terry White Chemists Indapamide SR, TW* – **INDAPAMIDE**, indapamide hemihydrate 1.5 mg modified release tablet, 90

8246B *Abisart, AF* – **IRBESARTAN**, irbesartan 75 mg tablet, 30

8247C *Abisart, AF* – **IRBESARTAN**, irbesartan 150 mg tablet, 30

8248D *Abisart, AF* – **IRBESARTAN**, irbesartan 300 mg tablet, 30

8404H *Abisart HCT 150/12.5, AF* – **IRBESARTAN + HYDROCHLOROTHIAZIDE**, irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30

8405J *Abisart HCT 300/12.5, AF* – **IRBESARTAN + HYDROCHLOROTHIAZIDE**, irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30

2136K *Abisart HCT 300/25, AF* – **IRBESARTAN + HYDROCHLOROTHIAZIDE**, irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30

8534E *Chem mart Lercanidipine, CH* – **LERCANIDIPINE**, lercanidipine hydrochloride 10 mg tablet, 28

8534E *Terry White Chemists Lercanidipine, TW* – **LERCANIDIPINE**, lercanidipine hydrochloride 10 mg tablet, 28

8679T *Chem mart Lercanidipine, CH* – **LERCANIDIPINE**, lercanidipine hydrochloride 20 mg tablet, 28

8679T *Terry White Chemists Lercanidipine, TW* – **LERCANIDIPINE**, lercanidipine hydrochloride 20 mg tablet, 28

8245Y *Chem mart Letrozole, CH* – **LETROZOLE**, letrozole 2.5 mg tablet, 30

8245Y *Terry White Chemists Letrozole, TW* – **LETROZOLE**, letrozole 2.5 mg tablet, 30

2430X *Formet Aspen 500, RW* – **METFORMIN**, metformin hydrochloride 500 mg tablet, 100

1801T *Formet Aspen 850, RW* – **METFORMIN**, metformin hydrochloride 850 mg tablet, 60

8732N *Toprol-XL 23.75, AP* – **METOPROLOL SUCCINATE**, METOPROLOL SUCCINATE Tablet 23.75 mg (controlled release), 15

1900B *GenRx Moclobemide, GX* – **MOCLOBEMIDE**, moclobemide 150 mg tablet, 60

8170B *Chem mart Olanzapine, CH* – **OLANZAPINE**, olanzapine 2.5 mg tablet, 28

8170B *Terry White Chemists Olanzapine, TW* – **OLANZAPINE**, olanzapine 2.5 mg tablet, 28

8185T *Chem mart Olanzapine, CH* – **OLANZAPINE**, olanzapine 5 mg tablet, 28

8185T *Terry White Chemists Olanzapine, TW* – **OLANZAPINE**, olanzapine 5 mg tablet, 28

8186W *Chem mart Olanzapine, CH* – **OLANZAPINE**, olanzapine 7.5 mg tablet, 28

8186W *Terry White Chemists Olanzapine, TW* – **OLANZAPINE**, olanzapine 7.5 mg tablet, 28

8187X	<i>Chem mart Olanzapine, CH</i> – OLANZAPINE , olanzapine 10 mg tablet, 28
8187X	<i>Terry White Chemists Olanzapine, TW</i> – OLANZAPINE , olanzapine 10 mg tablet, 28
11683X	<i>Chem mart Omeprazole, CH</i> – OMEPRAZOLE , omeprazole 20 mg enteric tablet, 30
11683X	<i>Terry White Chemists Omeprazole, TW</i> – OMEPRAZOLE , omeprazole 20 mg enteric tablet, 30
8331L	<i>Chem mart Omeprazole, CH</i> – OMEPRAZOLE , omeprazole 20 mg enteric tablet, 30
8331L	<i>Terry White Chemists Omeprazole, TW</i> – OMEPRAZOLE , omeprazole 20 mg enteric tablet, 30
8333N	<i>Chem mart Omeprazole, CH</i> – OMEPRAZOLE , omeprazole 20 mg enteric tablet, 30
8333N	<i>Terry White Chemists Omeprazole, TW</i> – OMEPRAZOLE , omeprazole 20 mg enteric tablet, 30
8694N	<i>Chem mart Pioglitazone, CH</i> – PIOGLITAZONE , pioglitazone 15 mg tablet, 28
8694N	<i>Terry White Chemists Pioglitazone, TW</i> – PIOGLITAZONE , pioglitazone 15 mg tablet, 28
8695P	<i>Chem mart Pioglitazone, CH</i> – PIOGLITAZONE , pioglitazone 30 mg tablet, 28
8695P	<i>Terry White Chemists Pioglitazone, TW</i> – PIOGLITAZONE , pioglitazone 30 mg tablet, 28
8696Q	<i>Chem mart Pioglitazone, CH</i> – PIOGLITAZONE , pioglitazone 45 mg tablet, 28
8696Q	<i>Terry White Chemists Pioglitazone, TW</i> – PIOGLITAZONE , pioglitazone 45 mg tablet, 28
9121C	<i>Chem mart Ramipril, CH</i> – RAMIPRIL , ramipril 2.5 mg capsule, 30
9121C	<i>Terry White Chemists Ramipril, TW</i> – RAMIPRIL , ramipril 2.5 mg capsule, 30
9122D	<i>Chem mart Ramipril, CH</i> – RAMIPRIL , ramipril 5 mg capsule, 30
9122D	<i>Terry White Chemists Ramipril, TW</i> – RAMIPRIL , ramipril 5 mg capsule, 30
8470T	<i>Chem mart Ramipril, CH</i> – RAMIPRIL , ramipril 10 mg capsule, 30
8470T	<i>Terry White Chemists Ramipril, TW</i> – RAMIPRIL , ramipril 10 mg capsule, 30
1945J	<i>Chem mart Ramipril, CH</i> – RAMIPRIL , ramipril 2.5 mg tablet, 30
1945J	<i>Terry White Chemists Ramipril, TW</i> – RAMIPRIL , ramipril 2.5 mg tablet, 30
1946K	<i>Chem mart Ramipril, CH</i> – RAMIPRIL , ramipril 5 mg tablet, 30
1946K	<i>Terry White Chemists Ramipril, TW</i> – RAMIPRIL , ramipril 5 mg tablet, 30
1849H	<i>Chem mart Sumatriptan, CH</i> – SUMATRIPTAN , sumatriptan 50 mg tablet, 4
1849H	<i>Terry White Chemists Sumatriptan, TW</i> – SUMATRIPTAN , sumatriptan 50 mg tablet, 4
8144P	<i>Chem mart Sumatriptan, CH</i> – SUMATRIPTAN , sumatriptan 50 mg tablet, 2
8144P	<i>Terry White Chemists Sumatriptan, TW</i> – SUMATRIPTAN , sumatriptan 50 mg tablet, 2
5480K	<i>Chem mart Valaciclovir, CH</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 30
5480K	<i>Terry White Chemists Valaciclovir, TW</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 30
8064K	<i>Chem mart Valaciclovir, CH</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 42
8064K	<i>Terry White Chemists Valaciclovir, TW</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 42
8134D	<i>Chem mart Valaciclovir, CH</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 30
8134D	<i>Terry White Chemists Valaciclovir, TW</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 30

Alterations

Alteration – Item Description

From

2181T **SODIUM HYALURONATE**, sodium hyaluronate 0.1% (1 mg/mL) eye drops, 10 mL (*Hylo-Fresh*)

To

2181T **HYALURONATE SODIUM**, hyaluronate sodium 0.1% eye drops, 10 mL (*Hylo-Fresh*)

From

2184Y **SODIUM HYALURONATE**, sodium hyaluronate 0.1% (1 mg/mL) eye drops, 10 mL (*Hylo-Fresh*)

To

2184Y **HYALURONATE SODIUM**, hyaluronate sodium 0.1% eye drops, 10 mL (*Hylo-Fresh*)

From

2171G **SODIUM HYALURONATE**, sodium hyaluronate 0.2% (2 mg/mL) eye drops, 10 mL (*Hylo-Forte*)

To

2171G **HYALURONATE SODIUM**, hyaluronate sodium 0.2% eye drops, 10 mL (*Hylo-Forte*)

From
2253N **SODIUM HYALURONATE**, sodium hyaluronate 0.2% (2 mg/mL) eye drops, 10 mL (*Hilo-Forte*)
To
2253N **HYALURONATE SODIUM**, hyaluronate sodium 0.2% eye drops, 10 mL (*Hilo-Forte*)

From
2870C **WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, LONG CHAIN POLYUNSATURATED FATTY ACIDS, VITAMINS AND MINERALS, LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE**, whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, low in protein, phosphate, potassium and lactose oral liquid: powder for, 6 x 400 g cans (*Renastart*)
To
2870C **WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, LONG CHAIN POLYUNSATURATED FATTY ACIDS, VITAMINS AND MINERALS, LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE**, whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, low in protein, phosphate, potassium and lactose powder for oral liquid, 6 x 400 g cans (*Renastart*)

Alteration – Brand Name

From
1746X *Generic Health Pty Ltd, GQ – PARACETAMOL*, paracetamol 500 mg tablet, 100
To
1746X *Paracetamol Generic Health, GQ – PARACETAMOL*, paracetamol 500 mg tablet, 100

From
5196L *Generic Health Pty Ltd, GQ – PARACETAMOL*, paracetamol 500 mg tablet, 100
To
5196L *Paracetamol Generic Health, GQ – PARACETAMOL*, paracetamol 500 mg tablet, 100

From
5224Y *Generic Health Pty Ltd, GQ – PARACETAMOL*, paracetamol 500 mg tablet, 100
To
5224Y *Paracetamol Generic Health, GQ – PARACETAMOL*, paracetamol 500 mg tablet, 100

From
8784H *Generic Health Pty Ltd, GQ – PARACETAMOL*, paracetamol 500 mg tablet, 100
To
8784H *Paracetamol Generic Health, GQ – PARACETAMOL*, paracetamol 500 mg tablet, 100

Advance Notices

1 August 2019

Deletion – Brand

2518M *Emend, MK – APREPITANT*, aprepitant 165 mg capsule, 1
1153Q *Carbimazol ARISTO, PQ – CARBIMAZOLE*, carbimazole 5 mg tablet, 100
1335G *Diltiazem Sandoz, SZ – DILTIAZEM*, diltiazem hydrochloride 60 mg tablet, 90
2424N *E.E.S. 200, GH – ERYTHROMYCIN ETHYLSUCCINATE*, erythromycin (as ethylsuccinate) 200 mg/5 mL powder for oral liquid, 100 mL
2428T *E.E.S. Granules, GH – ERYTHROMYCIN ETHYLSUCCINATE*, erythromycin (as ethylsuccinate) 400 mg/5 mL powder for oral liquid, 100 mL
3334L *E.E.S. 200, GH – ERYTHROMYCIN ETHYLSUCCINATE*, erythromycin (as ethylsuccinate) 200 mg/5 mL powder for oral liquid, 100 mL
3337P *E.E.S. Granules, GH – ERYTHROMYCIN ETHYLSUCCINATE*, erythromycin (as ethylsuccinate) 400 mg/5 mL powder for oral liquid, 100 mL
2412Y *Frusemide Sandoz, SZ – FUROSEMIDE (FRUSEMIDE)*, furosemide (frusemide) 40 mg tablet, 100
1280J *Hydrene 25/50, AF – HYDROCHLOROTHIAZIDE + TRIAMTERENE*, hydrochlorothiazide 25 mg + triamterene 50 mg tablet, 100
2946C *Phosphate Sandoz, FF – PHOSPHORUS*, phosphorus 500 mg effervescent tablet, 100

1 September 2019

Deletion – Brand

1923F *MMA/PA cooler 15, VF – AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, THREONINE AND VALINE AND LOW IN ISOLEUCINE*, amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid, 30 x 130 mL pouches
1711C *Hypurin Isophane, AS – INSULIN ISOPHANE BOVINE*, insulin isophane bovine 100 units/mL injection, 1 x 10 mL vial
1713E *Hypurin Neutral, AS – INSULIN NEUTRAL BOVINE*, insulin neutral bovine 100 units/mL injection, 1 x 10 mL vial

1 October 2019

Deletion – Brand

2544X *Akineton, GH* – **BIPERIDEN**, biperiden hydrochloride 2 mg tablet, 100

1 December 2019

Deletion – Brand

1002R *Zovirax, GK* – **ACICLOVIR**, aciclovir 3% eye ointment, 4.5 g

5501M *Zovirax, GK* – **ACICLOVIR**, aciclovir 3% eye ointment, 4.5 g

1 January 2020

Deletion – Brand

8362D *Capecitabine Apotex, TX* – **CAPECITABINE**, capecitabine 500 mg tablet, 120

Highly Specialised Drugs Program (Private Hospital)

Additions

Addition – Brand

6371H *DEZTRON, DZ* – **ZOLEDRONIC ACID**, zoledronic acid 4 mg/5 mL injection, 5 mL vial

Deletions

Deletion – Brand

6429J *Bosentan APOTEX, TX* – **BOSENTAN**, bosentan 62.5 mg tablet, 60

6430K *Bosentan APOTEX, TX* – **BOSENTAN**, bosentan 125 mg tablet, 60

Alterations

Alteration – Note

11167R **PEGVISOMANT**, pegvisomant 10 mg injection [30 vials] (& inert substance diluent [30 syringes], 1 pack (*Somavert*))

11172B **PEGVISOMANT**, pegvisomant 15 mg injection [30 vials] (& inert substance diluent [30 syringes], 1 pack (*Somavert*))

11166Q **PEGVISOMANT**, pegvisomant 20 mg injection [1 vial] (& inert substance diluent [1 syringe], 1 pack (*Somavert*))

11174D **PEGVISOMANT**, pegvisomant 20 mg injection [30 vials] (& inert substance diluent [30 syringes], 1 pack (*Somavert*))

Alteration – Restriction

10880P **PASIREOTIDE**, pasireotide 20 mg modified release injection [1 vial] (& inert substance diluent [2 mL syringe], 1 pack (*Signifor LAR*))

10884W **PASIREOTIDE**, pasireotide 40 mg modified release injection [1 vial] (& inert substance diluent [2 mL syringe], 1 pack (*Signifor LAR*))

10887B **PASIREOTIDE**, pasireotide 60 mg modified release injection [1 vial] (& inert substance diluent [2 mL syringe], 1 pack (*Signifor LAR*))

11167R **PEGVISOMANT**, pegvisomant 10 mg injection [30 vials] (& inert substance diluent [30 syringes], 1 pack (*Somavert*))

11172B **PEGVISOMANT**, pegvisomant 15 mg injection [30 vials] (& inert substance diluent [30 syringes], 1 pack (*Somavert*))

11166Q **PEGVISOMANT**, pegvisomant 20 mg injection [1 vial] (& inert substance diluent [1 syringe], 1 pack (*Somavert*))

11174D **PEGVISOMANT**, pegvisomant 20 mg injection [30 vials] (& inert substance diluent [30 syringes], 1 pack (*Somavert*))

Highly Specialised Drugs Program (Public Hospital)

Additions

Addition – Brand

9653C *DEZTRON, DZ* – **ZOLEDRONIC ACID**, zoledronic acid 4 mg/5 mL injection, 5 mL vial

Deletions

Deletion – Brand

5618Q *Bosentan APOTEX, TX* – **BOSENTAN**, bosentan 62.5 mg tablet, 60

5619R *Bosentan APOTEX, TX* – **BOSENTAN**, bosentan 125 mg tablet, 60

Alterations

Alteration – Note

- 11179J **PEGVISOMANT**, pegvisomant 10 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack (Somavert)
- 11173C **PEGVISOMANT**, pegvisomant 15 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack (Somavert)
- 11177G **PEGVISOMANT**, pegvisomant 20 mg injection [1 vial] (&) inert substance diluent [1 syringe], 1 pack (Somavert)
- 11181L **PEGVISOMANT**, pegvisomant 20 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack (Somavert)

Alteration – Restriction

- 10886Y **PASIREOTIDE**, pasireotide 20 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack (Signifor LAR)
- 10883T **PASIREOTIDE**, pasireotide 40 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack (Signifor LAR)
- 10882R **PASIREOTIDE**, pasireotide 60 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack (Signifor LAR)
- 11179J **PEGVISOMANT**, pegvisomant 10 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack (Somavert)
- 11173C **PEGVISOMANT**, pegvisomant 15 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack (Somavert)
- 11177G **PEGVISOMANT**, pegvisomant 20 mg injection [1 vial] (&) inert substance diluent [1 syringe], 1 pack (Somavert)
- 11181L **PEGVISOMANT**, pegvisomant 20 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack (Somavert)

Highly Specialised Drugs Program (Community Access)

Deletions

Deletion – Item

- 10300D **RITONAVIR**, ritonavir 600 mg/7.5 mL oral liquid, 90 mL (Norvir)

Advance Notices

1 January 2020

Deletion – Brand

- 10357D **Abacavir/Lamivudine 600/300 APOTEX, TX – ABACAVIR + LAMIVUDINE**, abacavir 600 mg + lamivudine 300 mg tablet, 30

Opiate Dependence Treatment Program

Alterations

Alteration – Item Description

From

- 6309C **BUPRENORPHINE**, buprenorphine 8 mg tablet, 7 (Subutex)

To

- 6309C **BUPRENORPHINE**, buprenorphine 8 mg sublingual tablet, 7 (Subutex)

Repatriation Pharmaceutical Benefits

Additions

Addition – Item

- 11714M **BANDAGE COMPRESSION**, bandage compression 10 cm x 3.5 m soft bandage [1] (&) bandage compression 10 cm x 6 m short stretch bandage [1], 1 pack (Rosidal TCS 26484)
- 11709G **DRESSING HYDROGEL**, dressing hydrogel 10 cm x 10 cm dressing, 5 (Suprasorb G 33631)
- 11717Q **DRESSING NON-ADHERENT ABSORBENT**, dressing non-adherent absorbent 12.5 cm x 12.5 cm hydroactive dressing, 10 (Vliwasorb Pro 32641)
- 11715N **DRESSING NON-ADHERENT ABSORBENT**, dressing non-adherent absorbent 22 cm x 22 cm hydroactive dressing, 10 (Vliwasorb Pro 32643)
- 11718R **DRESSING NON-ADHERENT ABSORBENT**, dressing non-adherent absorbent 22 cm x 32 cm hydroactive dressing, 10 (Vliwasorb Pro 32644)

- 11708F **GLYCEROL**, glycerol 15% solution, 1 kg (*QV Gentle Wash*)
- 11712K **GLYCEROL + WHITE SOFT PARAFFIN**, glycerol 5% + white soft paraffin 5% lotion, 1 L (*QV Skin Lotion*)
- 11710H **HYDROCORTISONE ACETATE**, hydrocortisone acetate 1% cream, 30 g (*Pharmacy Action Hydrocortisone Cream 1%*)
- 11707E **METHYL SALICYLATE + MENTHOL + CAMPHOR + EUCALYPTUS OIL + PINE OIL PUMILIO + TURPENTINE OIL + PEPPERMINT OIL + CAJUPUT OIL + CAPSICUM ANNUUM**, methyl salicylate 20% + menthol 5% + camphor 3.5% + eucalyptus oil 3% + pine oil pumilio 1% + turpentine oil 1% + peppermint oil 0.5% + cajuput oil 0.5% + capsicum annuum 0.15% cream, 100 g (*Goanna Heat Cream*)
- 11711J **OXYMETAZOLINE**, oxymetazoline hydrochloride 0.05% nasal spray, 20 mL (*Pharmacy Action Nasal Decongestant*)

Addition – Brand

- 4591P *Gabapentin APOTEX, TY* – **GABAPENTIN**, gabapentin 100 mg capsule, 100
- 4592Q *Gabapentin APOTEX, TY* – **GABAPENTIN**, gabapentin 300 mg capsule, 100
- 4593R *Gabapentin APOTEX, TY* – **GABAPENTIN**, gabapentin 400 mg capsule, 100
- 4594T *Gabapentin APOTEX, TY* – **GABAPENTIN**, gabapentin 600 mg tablet, 100
- 4595W *Gabapentin APOTEX, TY* – **GABAPENTIN**, gabapentin 800 mg tablet, 100
- 4328T *APO-Mebeverine, TX* – **MEBEVERINE**, mebeverine hydrochloride 135 mg tablet, 90
- 10598T *Pharmacy Action Paracetamol Osteo 665, GQ* – **PARACETAMOL**, paracetamol 665 mg modified release tablet, 96

Addition – Equivalence Indicator

- 10598T *Osteomol 665 Paracetamol, CR* – **PARACETAMOL**, paracetamol 665 mg modified release tablet, 96

Alterations

Alteration – Brand Name

From

- 10582Y *Generic Health Pty Ltd, GQ* – **PARACETAMOL**, paracetamol 500 mg tablet, 100

To

- 10582Y *Paracetamol Generic Health, GQ* – **PARACETAMOL**, paracetamol 500 mg tablet, 100

From

- 10585D *Generic Health Pty Ltd, GQ* – **PARACETAMOL**, paracetamol 500 mg tablet, 100

To

- 10585D *Paracetamol Generic Health, GQ* – **PARACETAMOL**, paracetamol 500 mg tablet, 100

General Pharmaceutical Benefits

■ ISOTRETINOIN

Caution This drug causes birth defects.

This drug has been reported to cause other frequent and potentially serious toxicity.

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

Authority required (STREAMLINED)

5224

Severe cystic acne

Clinical criteria:

- The condition must be unresponsive to other therapy.

isotretinoin 5 mg capsule, 60

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11716P	1	3	..	23.32	24.57	Oratane [OU]

■ PHENELZINE

Caution This drug is an irreversible monoamine oxidase inhibitor.

Restricted benefit

Depression

Clinical criteria:

- The treatment must be for when all other anti-depressant therapy has failed; OR
- The treatment must be for when all other anti-depressant therapy is inappropriate.

phenelzine 15 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11713L	1.7	1	..	*112.45	40.30	^a Nardil [LM]

Highly Specialised Drugs Program (Private Hospital)

▪ PASIREOTIDE

Caution Careful monitoring of patients is mandatory due to high risk of developing hyperglycaemia

Note Special Pricing Arrangements apply.

Authority required

Acromegaly

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have a mean growth hormone (GH) level greater than 1 micrograms per litre or 3 mIU/L, **AND**
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than the upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

Population criteria:

- Patient must be aged 18 years or older.

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as:

- 1) Growth hormone level greater than 1 mcg/L or 3 mIU/L; OR
- 2) IGF-1 level is greater than the age- and sex-adjusted ULN.

In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:

- 1) Growth hormone (GH) levels of less than 2.5 mcg/L; and
- 2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

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

- a) a completed authority prescription form; and
- b) a completed Acromegaly PBS Authority Application - Supporting Information Form; and
- c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; and a copy of GH and IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided; and
- d) a recent copy of GH and IGF-1 levels must be provided.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Acromegaly

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

Population criteria:

- Patient must be aged 18 years or older.

In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:

- 1) Growth hormone (GH) levels of less than 2.5 mcg/L; and
- 2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

In a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy and the GH and IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided at the time of approval.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

pasireotide 20 mg modified release injection [1 vial] (& inert substance diluent [2 mL syringe], 1 pack

10880P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*7847.39	Signifor LAR [NV]

pasireotide 40 mg modified release injection [1 vial] (& inert substance diluent [2 mL syringe], 1 pack

10884W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*7847.39	Signifor LAR [NV]

pasireotide 60 mg modified release injection [1 vial] (& inert substance diluent [2 mL syringe], 1 pack

10887B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*7847.39	Signifor LAR [NV]

▪ PEGVISOMANT

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

Note Special Pricing Arrangements apply.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs Programs

Reply Paid 9826

HOBART TAS 7001

Authority required

Acromegaly

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than the upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue.

Somatostatin analogues include octreotide, lanreotide and pasireotide

Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as:

- 1) Growth hormone level greater than 1 mcg/L or 3 mIU/L; OR
- 2) IGF-1 level is greater than the age- and sex-adjusted ULN.

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).

Two completed authority prescriptions should be submitted with the initial application for this drug. One prescription should be for the loading dose of 80 mg for a quantity of 4 vials of 20 mg with no repeats. The second prescription should be for subsequent doses, starting from 10 mg daily, and allowing dose adjustments in increments of 5 mg based on serum IGF-1

levels measured every 4 to 6 weeks in order to maintain the serum IGF-1 level within the age-adjusted normal range based on the dosage recommendations in the TGA-approved Product Information.

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

- a) two completed authority prescription forms ; and
- b) a completed Acromegaly Pegvisomant initial PBS Authority Application - Supporting Information Form; and
- c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy, the date and result of IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy; and
- d) a recent result of the IGF-1 level and the date of assessment ; and
- e) demonstration of failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide

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

pegvisomant 20 mg injection [1 vial] (& inert substance diluent [1 syringe], 1 pack

11166Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	*586.83	Somavert [PF]

▪ PEGVISOMANT

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

Note Special Pricing Arrangements apply.

Authority required

Acromegaly

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than the upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue.

Somatostatin analogues include octreotide, lanreotide and pasireotide

Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as:

- 1) Growth hormone level greater than 1 mcg/L or 3 mIU/L; OR
- 2) IGF-1 level is greater than the age- and sex-adjusted ULN.

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).

Two completed authority prescriptions should be submitted with the initial application for this drug. One prescription should be for the loading dose of 80 mg for a quantity of 4 vials of 20 mg with no repeats. The second prescription should be for subsequent doses, starting from 10 mg daily, and allowing dose adjustments in increments of 5 mg based on serum IGF-1 levels measured every 4 to 6 weeks in order to maintain the serum IGF-1 level within the age-adjusted normal range based on the dosage recommendations in the TGA-approved Product Information.

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

- a) two completed authority prescription forms ; and
- b) a completed Acromegaly Pegvisomant initial PBS Authority Application - Supporting Information Form; and
- c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy, the date and result of IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy; and
- d) a recent result of the IGF-1 level and the date of assessment ; and
- e) demonstration of failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide

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

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

Authority required

Acromegaly

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue, **AND**
- The treatment must cease if IGF-1 is not lower after 3 months of pegvisomant treatment at the maximum tolerated dose. Somatostatin analogues include octreotide, lanreotide and pasireotide

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1). In a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; and a copy of IGF-1 level taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided at the time of application.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

pegvisomant 10 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack

11167R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	4225.96	Somavert [PF]

pegvisomant 15 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack

11172B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	4225.96	Somavert [PF]

pegvisomant 20 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack

11174D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	4225.96	Somavert [PF]

Highly Specialised Drugs Program (Public Hospital)

▪ PASIREOTIDE

Caution Careful monitoring of patients is mandatory due to high risk of developing hyperglycaemia

Note Special Pricing Arrangements apply.

Authority required

Acromegaly

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have a mean growth hormone (GH) level greater than 1 micrograms per litre or 3 mIU/L, **AND**
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than the upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

Population criteria:

- Patient must be aged 18 years or older.

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as:

- 1) Growth hormone level greater than 1 mcg/L or 3 mIU/L; OR
- 2) IGF-1 level is greater than the age- and sex-adjusted ULN.

In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:

- 1) Growth hormone (GH) levels of less than 2.5 mcg/L; and
- 2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

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

- a) a completed authority prescription form; and
- b) a completed Acromegaly PBS Authority Application - Supporting Information Form; and
- c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; and a copy of GH and IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided; and
- d) a recent copy of GH and IGF-1 levels must be provided.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Acromegaly

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

Population criteria:

- Patient must be aged 18 years or older.

In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:

- 1) Growth hormone (GH) levels of less than 2.5 mcg/L; and
- 2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

In a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy and the GH and IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided at the time of approval.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

pasireotide 20 mg modified release injection [1 vial] (& inert substance diluent [2 mL syringe], 1 pack

10886Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*7800.00	Signifor LAR [NV]

pasireotide 40 mg modified release injection [1 vial] (& inert substance diluent [2 mL syringe], 1 pack

10883T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*7800.00	Signifor LAR [NV]

pasireotide 60 mg modified release injection [1 vial] (& inert substance diluent [2 mL syringe], 1 pack

10882R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*7800.00	Signifor LAR [NV]

▪ PEGVISOMANT

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

Note Special Pricing Arrangements apply.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs Programs

Reply Paid 9826

HOBART TAS 7001

Authority required

Acromegaly

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than the upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue.

Somatostatin analogues include octreotide, lanreotide and pasireotide

Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as:

- 1) Growth hormone level greater than 1 mcg/L or 3 mIU/L; OR
- 2) IGF-1 level is greater than the age- and sex-adjusted ULN.

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).

Two completed authority prescriptions should be submitted with the initial application for this drug. One prescription should be for the loading dose of 80 mg for a quantity of 4 vials of 20 mg with no repeats. The second prescription should be for subsequent doses, starting from 10 mg daily, and allowing dose adjustments in increments of 5 mg based on serum IGF-1

levels measured every 4 to 6 weeks in order to maintain the serum IGF-1 level within the age-adjusted normal range based on the dosage recommendations in the TGA-approved Product Information.

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

- a) two completed authority prescription forms ; and
- b) a completed Acromegaly Pegvisomant initial PBS Authority Application - Supporting Information Form; and
- c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy, the date and result of IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy; and
- d) a recent result of the IGF-1 level and the date of assessment ; and
- e) demonstration of failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide

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

pegvisomant 20 mg injection [1 vial] (& inert substance diluent [1 syringe], 1 pack

11177G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	*557.16	Somavert [PF]

▪ PEGVISOMANT

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

Note Special Pricing Arrangements apply.

Authority required

Acromegaly

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than the upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue.

Somatostatin analogues include octreotide, lanreotide and pasireotide

Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as:

- 1) Growth hormone level greater than 1 mcg/L or 3 mIU/L; OR
- 2) IGF-1 level is greater than the age- and sex-adjusted ULN.

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).

Two completed authority prescriptions should be submitted with the initial application for this drug. One prescription should be for the loading dose of 80 mg for a quantity of 4 vials of 20 mg with no repeats. The second prescription should be for subsequent doses, starting from 10 mg daily, and allowing dose adjustments in increments of 5 mg based on serum IGF-1 levels measured every 4 to 6 weeks in order to maintain the serum IGF-1 level within the age-adjusted normal range based on the dosage recommendations in the TGA-approved Product Information.

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

- a) two completed authority prescription forms ; and
- b) a completed Acromegaly Pegvisomant initial PBS Authority Application - Supporting Information Form; and
- c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy, the date and result of IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy; and
- d) a recent result of the IGF-1 level and the date of assessment ; and
- e) demonstration of failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide

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

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs Programs

Reply Paid 9826

HOBART TAS 7001

Authority required

Acromegaly

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue, **AND**
- The treatment must cease if IGF-1 is not lower after 3 months of pegvisomant treatment at the maximum tolerated dose. Somatostatin analogues include octreotide, lanreotide and pasireotide

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1). In a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; and a copy of IGF-1 level taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided at the time of application.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

pegvisomant 10 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
11179J	1	5	..	4178.57	Somavert [PF]

pegvisomant 15 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
11173C	1	5	..	4178.57	Somavert [PF]

pegvisomant 20 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
11181L	1	5	..	4178.57	Somavert [PF]

Repatriation Pharmaceutical Benefits Scheme

▪ BANDAGE COMPRESSION

bandage compression 10 cm x 3.5 m soft bandage [1] (&) bandage compression 10 cm x 6 m short stretch bandage [1], 1 pack

11714M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	38.07	6.50	Rosidal TCS 26484 [LC]

▪ DRESSING HYDROGEL

dressing hydrogel 10 cm x 10 cm dressing, 5

11709G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	30.03	6.50	Suprasorb G 33631 [LC]

▪ DRESSING NON-ADHERENT ABSORBENT

dressing non-adherent absorbent 12.5 cm x 12.5 cm hydroactive dressing, 10

11717Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	25.67	6.50	Vliwasorb Pro 32641 [LC]

dressing non-adherent absorbent 22 cm x 22 cm hydroactive dressing, 10

11715N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	36.53	6.50	Vliwasorb Pro 32643 [LC]

dressing non-adherent absorbent 22 cm x 32 cm hydroactive dressing, 10

11718R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	49.11	6.50	Vliwasorb Pro 32644 [LC]

▪ GLYCEROL

glycerol 15% solution, 1 kg

11708F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	30.19	6.50	QV Gentle Wash [EO]

▪ GLYCEROL + WHITE SOFT PARAFFIN

glycerol 5% + white soft paraffin 5% lotion, 1 L

11712K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	30.68	6.50	QV Skin Lotion [EO]

▪ HYDROCORTISONE ACETATE

hydrocortisone acetate 1% cream, 30 g

11710H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	16.65	6.50	Pharmacy Action Hydrocortisone Cream 1% [GQ]

▪ METHYL SALICYLATE + MENTHOL + CAMPHOR + EUCALYPTUS OIL + PINE OIL PUMILIO + TURPENTINE OIL + PEPPERMINT OIL + CAJUPUT OIL + CAPSICUM ANNUUM

methyl salicylate 20% + menthol 5% + camphor 3.5% + eucalyptus oil 3% + pine oil pumilio 1% + turpentine oil 1% + peppermint oil 0.5% + cajuput oil 0.5% + capsicum annuum 0.15% cream, 100 g

11707E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	18.09	6.50	Goanna Heat Cream [GQ]

▪ **OXYMETAZOLINE**

oxymetazoline hydrochloride 0.05% nasal spray, 20 mL

11711J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	20.47	6.50	Pharmacy Action Nasal Decongestant [GQ]
