Australian Government

Department of Health

PBS

Schedule of Pharmaceutical Benefits

Summary of Changes

Effective 1 August 2017

Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 August 2017 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	$7.15
	Dangerous drug fee	$3.01
	Extemporaneously-prepared	$9.19
	Allowable additional patient charge*	$4.38
Additional Fees (for safety net prices):	Ready-prepared	$1.21
	Extemporaneously-prepared	$1.57
Patient Co-payments:	General	$38.80
	Concessional	$6.30
Safety Net Thresholds:	General	$1494.90
	Concessional	$378.00
Safety Net Card Issue Fee:		$9.73

* The allowable additional patient charge is a discretionary charge to general patients if a pharmaceutical item has a dispensed price for maximum quantity less than the general patient co-payment. The pharmacist may charge general patients the allowable additional fee but the fee cannot take the cost of the prescription above the general patient co-payment for the medicine. This fee does not count towards the Safety Net threshold.

Summary of Changes

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 August 2017. The Schedule is updated on the first day of each month and is available on the internet at www.pbs.gov.au.

Prescriber Bag

Advance Notices

1 September 2017

Deletion – Brand

3497C *Ventolin Nebules, GK* – **SALBUTAMOL**, salbutamol 5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules

1 October 2017

Deletion – Brand

3496B *Ventolin Nebules, GK* – **SALBUTAMOL**, salbutamol 2.5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules

General Pharmaceutical Benefits

Additions

Addition – Item

11151X **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE**, amino acid formula with vitamins and minerals without phenylalanine and tyrosine powder for oral liquid, 30 x 34 g sachets *(TYR express 20)*

11148R **HUMAN CHORIONIC GONADOTROPHIN**, human chorionic gonadotrophin 1500 units injection [3 vials] (&) inert substance diluent [3 x 1 mL vials], 1 pack *(Pregnyl)*

11147Q **SOFOSBUVIR + VELPATASVIR**, sofosbuvir 400 mg + velpatasvir 100 mg tablet, 28 *(Epclusa)*

Addition – Brand

2751T *Amlodipine Amneal, EF* – **AMLODIPINE**, amlodipine 5 mg tablet, 30

2752W *Amlodipine Amneal, EF* – **AMLODIPINE**, amlodipine 10 mg tablet, 30

8717T *Aripiprazole AN, EA* – **ARIPIPRAZOLE**, aripiprazole 10 mg tablet, 30

8718W *Aripiprazole AN, EA* – **ARIPIPRAZOLE**, aripiprazole 15 mg tablet, 30

8719X *Aripiprazole AN, EA* – **ARIPIPRAZOLE**, aripiprazole 20 mg tablet, 30

8720Y *Aripiprazole AN, EA* – **ARIPIPRAZOLE**, aripiprazole 30 mg tablet, 30

10915L *Glivanib, JU* – **IMATINIB**, imatinib 100 mg capsule, 60

10918P *Glivanib, JU* – **IMATINIB**, imatinib 100 mg capsule, 60

10920R *Glivanib, JU* – **IMATINIB**, imatinib 100 mg capsule, 60

10924Y *Glivanib, JU* – **IMATINIB**, imatinib 100 mg capsule, 60

10940T *CIPLA IMATINIB ADULT, LR* – **IMATINIB**, imatinib 100 mg capsule, 60

10940T *Glivanib, JU* – **IMATINIB**, imatinib 100 mg capsule, 60

10941W *Glivanib, JU* – **IMATINIB**, imatinib 100 mg capsule, 60

10942X *Glivanib, JU* – **IMATINIB**, imatinib 100 mg capsule, 60

10916M *Glivanib, JU* – **IMATINIB**, imatinib 400 mg capsule, 30

10917N *Glivanib, JU* – **IMATINIB**, imatinib 400 mg capsule, 30

10921T *CIPLA IMATINIB ADULT, LR* – **IMATINIB**, imatinib 400 mg capsule, 30

10921T *Glivanib, JU* – **IMATINIB**, imatinib 400 mg capsule, 30

10925B *Glivanib, JU* – **IMATINIB**, imatinib 400 mg capsule, 30

10933K *Glivanib, JU* – **IMATINIB**, imatinib 400 mg capsule, 30

10935M *Glivanib, JU* – **IMATINIB**, imatinib 400 mg capsule, 30

10939R *Glivanib, JU* – **IMATINIB**, imatinib 400 mg capsule, 30

5553G *Lantim, JU* – **LATANOPROST + TIMOLOL**, latanoprost 0.005% + timolol 0.5% eye drops, 2.5 mL

8895E *Lantim, JU* – **LATANOPROST + TIMOLOL**, latanoprost 0.005% + timolol 0.5% eye drops, 2.5 mL

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

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

2348N *APO-Pregabalin, TX* – **PREGABALIN**, pregabalin 25 mg capsule, 56

2348N *LYPRALIN, RW* – **PREGABALIN**, pregabalin 25 mg capsule, 56

2348N *Lyzalon, AF* – **PREGABALIN**, pregabalin 25 mg capsule, 56

2348N *PREGABALIN-DRLA, RZ* – **PREGABALIN**, pregabalin 25 mg capsule, 56

2348N *Pregabalin APOTEX, GX* – **PREGABALIN**, pregabalin 25 mg capsule, 56

2348N *Pregabalin GH, GQ* – **PREGABALIN**, pregabalin 25 mg capsule, 56

2348N *Pregabalin Sandoz, SZ* – **PREGABALIN**, pregabalin 25 mg capsule, 56

2348N *Pregabalin-Teva, TB* – **PREGABALIN**, pregabalin 25 mg capsule, 56

2335X *APO-Pregabalin, TX* – **PREGABALIN**, pregabalin 75 mg capsule, 56

2335X *LYPRALIN, RW* – **PREGABALIN**, pregabalin 75 mg capsule, 56

2335X *Lyzalon, AF* – **PREGABALIN**, pregabalin 75 mg capsule, 56

2335X *PREGABALIN-DRLA, RZ* – **PREGABALIN**, pregabalin 75 mg capsule, 56

2335X *Pregabalin APOTEX, GX* – **PREGABALIN**, pregabalin 75 mg capsule, 56

2335X *Pregabalin GH, GQ* – **PREGABALIN**, pregabalin 75 mg capsule, 56

2335X *Pregabalin Sandoz, SZ* – **PREGABALIN**, pregabalin 75 mg capsule, 56

2335X *Pregabalin-Teva, TB* – **PREGABALIN**, pregabalin 75 mg capsule, 56

2355Y *APO-Pregabalin, TX* – **PREGABALIN**, pregabalin 150 mg capsule, 56

2355Y *LYPRALIN, RW* – **PREGABALIN**, pregabalin 150 mg capsule, 56

2355Y *Lyzalon, AF* – **PREGABALIN**, pregabalin 150 mg capsule, 56

2355Y *PREGABALIN-DRLA, RZ* – **PREGABALIN**, pregabalin 150 mg capsule, 56

2355Y *Pregabalin APOTEX, GX* – **PREGABALIN**, pregabalin 150 mg capsule, 56

2355Y *Pregabalin GH, GQ* – **PREGABALIN**, pregabalin 150 mg capsule, 56

2355Y *Pregabalin Sandoz, SZ* – **PREGABALIN**, pregabalin 150 mg capsule, 56

2355Y *Pregabalin-Teva, TB* – **PREGABALIN**, pregabalin 150 mg capsule, 56

2363J *APO-Pregabalin, TX* – **PREGABALIN**, pregabalin 300 mg capsule, 56

2363J *LYPRALIN, RW* – **PREGABALIN**, pregabalin 300 mg capsule, 56

2363J *Lyzalon, AF* – **PREGABALIN**, pregabalin 300 mg capsule, 56

2363J *PREGABALIN-DRLA, RZ* – **PREGABALIN**, pregabalin 300 mg capsule, 56

2363J *Pregabalin APOTEX, GX* – **PREGABALIN**, pregabalin 300 mg capsule, 56

2363J *Pregabalin GH, GQ* – **PREGABALIN**, pregabalin 300 mg capsule, 56

2363J *Pregabalin Sandoz, SZ* – **PREGABALIN**, pregabalin 300 mg capsule, 56

2363J *Pregabalin-Teva, TB* – **PREGABALIN**, pregabalin 300 mg capsule, 56

Addition – Equivalence Indicator

2522R *Allegron, RW* – **NORTRIPTYLINE**, nortriptyline 10 mg tablet, 50

2523T *Allegron, RW* – **NORTRIPTYLINE**, nortriptyline 25 mg tablet, 50

2348N *Lyrica, PF* – **PREGABALIN**, pregabalin 25 mg capsule, 56

2335X *Lyrica, PF* – **PREGABALIN**, pregabalin 75 mg capsule, 56

2355Y *Lyrica, PF* – **PREGABALIN**, pregabalin 150 mg capsule, 56

2363J *Lyrica, PF* – **PREGABALIN**, pregabalin 300 mg capsule, 56

Deletions

Deletion – Brand

5006L *AmoxyClav RBX 875/125, RA* – **AMOXYCILLIN + CLAVULANIC ACID**, amoxycillin 875 mg + clavulanic acid 125 mg tablet, 10

8254K *AmoxyClav RBX 875/125, RA* – **AMOXYCILLIN + CLAVULANIC ACID**, amoxycillin 875 mg + clavulanic acid 125 mg tablet, 10

8256M *Carvedilol generichealth, GQ* – **CARVEDILOL**, carvedilol 6.25 mg tablet, 60

5541P *APO-Dorzolamide, TX* – **DORZOLAMIDE**, dorzolamide 2% eye drops, 5 mL

8488R *APO-Dorzolamide, TX* – **DORZOLAMIDE**, dorzolamide 2% eye drops, 5 mL

5542Q *APO-Dorzolamide/Timolol 20/5, TX* – **DORZOLAMIDE + TIMOLOL**, dorzolamide 2% + timolol 0.5% eye drops, 5 mL

8567X *APO-Dorzolamide/Timolol 20/5, TX* – **DORZOLAMIDE + TIMOLOL**, dorzolamide 2% + timolol 0.5% eye drops, 5 mL

9155W *Duloxetine RBX, RA* – **DULOXETINE**, duloxetine 30 mg enteric capsule, 28

9156X *Duloxetine RBX, RA* – **DULOXETINE**, duloxetine 60 mg enteric capsule, 28

1434L *Fluoxetine RBX, RA* – **FLUOXETINE**, fluoxetine 20 mg capsule, 28

8170B *Lanzek, EL* – **OLANZAPINE**, olanzapine 2.5 mg tablet, 28

8185T *Lanzek, EL* – **OLANZAPINE**, olanzapine 5 mg tablet, 28

8186W *Lanzek, EL* – **OLANZAPINE**, olanzapine 7.5 mg tablet, 28

8187X *Lanzek, EL* – **OLANZAPINE**, olanzapine 10 mg tablet, 28

8433W *Lanzek Zydis, EL* – **OLANZAPINE**, olanzapine 5 mg wafer, 28

8434X *Lanzek Zydis, EL* – **OLANZAPINE**, olanzapine 10 mg wafer, 28

8331L *Omeprazole RBX, RA* – **OMEPRAZOLE**, omeprazole 20 mg enteric tablet, 30

8333N *Omeprazole RBX, RA* – **OMEPRAZOLE**, omeprazole 20 mg enteric tablet, 30

Alterations

Alteration – Restriction

The following items have additions, deletions or alterations to restrictions, notes and/or cautions.

10322G **CRIZOTINIB**, crizotinib 250 mg capsule, 60 *(Xalkori)*

10323H **CRIZOTINIB**, crizotinib 200 mg capsule, 60 *(Xalkori)*

1581F **HUMAN CHORIONIC GONADOTROPHIN**, human chorionic gonadotrophin 1500 units injection [3 ampoules] (&) inert substance diluent [3 x 1 mL ampoules], 1 pack *(Pregnyl)*

Alteration – Manufacturer Code

		From	*To*
8729K	*Kytril* – **GRANISETRON**, granisetron 3 mg/3 mL injection, 3 mL ampoule	RO	IX
8730L	*Kytril* – **GRANISETRON**, granisetron 3 mg/3 mL injection, 3 mL ampoule	RO	IX
8728J	*Kytril* – **GRANISETRON**, granisetron 2 mg tablet, 1	RO	IX
8873B	*Kytril* – **GRANISETRON**, granisetron 2 mg tablet, 5	RO	IX

Advance Notices

1 September 2017
Deletion – Brand

8422G *Dilaudid-HP, MF* – **HYDROMORPHONE**, hydromorphone hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules

1596B *Ondansetron-Claris, AE* – **ONDANSETRON**, ondansetron 4 mg/2 mL injection, 2 mL ampoule

1597C *Ondansetron-Claris, AE* – **ONDANSETRON**, ondansetron 8 mg/4 mL injection, 4 mL ampoule

8226Y *Ondansetron-Claris, AE* – **ONDANSETRON**, ondansetron 4 mg/2 mL injection, 2 mL ampoule

8227B *Ondansetron-Claris, AE* – **ONDANSETRON**, ondansetron 8 mg/4 mL injection, 4 mL ampoule

2001H *Ventolin Nebules, GK* – **SALBUTAMOL**, salbutamol 5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules

1 October 2017
Deletion – Brand

2593L *Ferrum H, AS* – **IRON POLYMALTOSE**, iron (as polymaltose) 100 mg/2 mL injection, 5 x 2 mL ampoules

2805P *Ferrum H, AS* – **IRON POLYMALTOSE**, iron (as polymaltose) 100 mg/2 mL injection, 5 x 2 mL ampoules

2000G *Ventolin Nebules, GK* – **SALBUTAMOL**, salbutamol 2.5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules

10062N *Astromide, FR* – **TEMOZOLOMIDE**, temozolomide 180 mg capsule, 5

2438H *Astromide, FR* – **TEMOZOLOMIDE**, temozolomide 180 mg capsule, 5

8378Y *Astromide, FR* – **TEMOZOLOMIDE**, temozolomide 5 mg capsule, 5

8379B *Astromide, FR* – **TEMOZOLOMIDE**, temozolomide 20 mg capsule, 5

8380C *Astromide, FR* – **TEMOZOLOMIDE**, temozolomide 100 mg capsule, 5

8381D *Astromide, FR* – **TEMOZOLOMIDE**, temozolomide 250 mg capsule, 5

8819E *Astromide, FR* – **TEMOZOLOMIDE**, temozolomide 5 mg capsule, 5

8820F *Astromide, FR* – **TEMOZOLOMIDE**, temozolomide 20 mg capsule, 5

8821G *Astromide, FR* – **TEMOZOLOMIDE**, temozolomide 100 mg capsule, 5

9361Q *Astromide, FR* – **TEMOZOLOMIDE**, temozolomide 140 mg capsule, 5

9362R *Astromide, FR* – **TEMOZOLOMIDE**, temozolomide 140 mg capsule, 5

1 November 2017
Deletion – Brand

1210Q *Ciprofloxacin-BW, GQ* – **CIPROFLOXACIN**, ciprofloxacin 750 mg tablet, 14

1 December 2017
Deletion – Brand

8883M *Avanza, MK* – **MIRTAZAPINE**, mirtazapine 45 mg tablet, 30

Highly Specialised Drugs Program (Private Hospital)

Additions

Addition – Item

11144M **SOFOSBUVIR + VELPATASVIR**, sofosbuvir 400 mg + velpatasvir 100 mg tablet, 28 *(Epclusa)*

Addition – Brand

6100C *Azacitidine Accord, OC* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

6138C *Azacitidine Accord, OC* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

6429J *APO-BOSENTAN, GX* – **BOSENTAN**, bosentan 62.5 mg tablet, 60

6429J *BOSENTAN-DRLA, RZ* – **BOSENTAN**, bosentan 62.5 mg tablet, 60

6429J *BOSLEER, RW* – **BOSENTAN**, bosentan 62.5 mg tablet, 60

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

6429J *Bosentan Mylan, AF* – **BOSENTAN**, bosentan 62.5 mg tablet, 60

6429J *Bosentan RBX, RA* – **BOSENTAN**, bosentan 62.5 mg tablet, 60

6429J *Bosentan Sandoz, SZ* – **BOSENTAN**, bosentan 62.5 mg tablet, 60

6430K *APO-BOSENTAN, GX* – **BOSENTAN**, bosentan 125 mg tablet, 60

6430K *BOSENTAN-DRLA, RZ* – **BOSENTAN**, bosentan 125 mg tablet, 60

6430K *BOSLEER, RW* – **BOSENTAN**, bosentan 125 mg tablet, 60

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

6430K *Bosentan GH, GQ* – **BOSENTAN**, bosentan 125 mg tablet, 60

6430K *Bosentan Mylan, AF* – **BOSENTAN**, bosentan 125 mg tablet, 60

6430K *Bosentan RBX, RA* – **BOSENTAN**, bosentan 125 mg tablet, 60

6430K *Bosentan Sandoz, SZ* – **BOSENTAN**, bosentan 125 mg tablet, 60

10057H *Renflexis, MK* – **INFLIXIMAB**, infliximab 100 mg injection, 1 vial

10184B *Renflexis, MK* – **INFLIXIMAB**, infliximab 100 mg injection, 1 vial

6397Q *Renflexis, MK* – **INFLIXIMAB**, infliximab 100 mg injection, 1 vial

6448J *Renflexis, MK* – **INFLIXIMAB**, infliximab 100 mg injection, 1 vial

6496X *Renflexis, MK* – **INFLIXIMAB**, infliximab 100 mg injection, 1 vial

9612X *Renflexis, MK* – **INFLIXIMAB**, infliximab 100 mg injection, 1 vial

9613Y *Renflexis, MK* – **INFLIXIMAB**, infliximab 100 mg injection, 1 vial

9617E *Renflexis, MK* – **INFLIXIMAB**, infliximab 100 mg injection, 1 vial

9674E *Renflexis, MK* – **INFLIXIMAB**, infliximab 100 mg injection, 1 vial

6357N *Valganciclovir AN, EA* – **VALGANCICLOVIR**, valganciclovir 450 mg tablet, 60

6357N *Valganciclovir Mylan, AF* – **VALGANCICLOVIR**, valganciclovir 450 mg tablet, 60

6357N *Valganciclovir Sandoz, SZ* – **VALGANCICLOVIR**, valganciclovir 450 mg tablet, 60

Addition – Equivalence Indicator

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

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

6357N *Valcyte, RO* – **VALGANCICLOVIR**, valganciclovir 450 mg tablet, 60

Alterations

Alteration – Restriction

The following items have additions, deletions or alterations to restrictions, notes and/or cautions.

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

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

Highly Specialised Drugs Program (Public Hospital)

Additions

Addition – Item

11145N **SOFOSBUVIR + VELPATASVIR**, sofosbuvir 400 mg + velpatasvir 100 mg tablet, 28 *(Epclusa)*

Addition – Brand

9597D *Azacitidine Accord, OC* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

9598E *Azacitidine Accord, OC* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

5618Q *APO-BOSENTAN, GX* – **BOSENTAN**, bosentan 62.5 mg tablet, 60

5618Q *BOSENTAN-DRLA, RZ* – **BOSENTAN**, bosentan 62.5 mg tablet, 60

5618Q *BOSLEER, RW* – **BOSENTAN**, bosentan 62.5 mg tablet, 60

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

5618Q *Bosentan Mylan, AF* – **BOSENTAN**, bosentan 62.5 mg tablet, 60

5618Q *Bosentan RBX, RA* – **BOSENTAN**, bosentan 62.5 mg tablet, 60

5618Q *Bosentan Sandoz, SZ* – **BOSENTAN**, bosentan 62.5 mg tablet, 60

5619R *APO-BOSENTAN, GX* – **BOSENTAN**, bosentan 125 mg tablet, 60

5619R *BOSENTAN-DRLA, RZ* – **BOSENTAN**, bosentan 125 mg tablet, 60

5619R *BOSLEER, RW* – **BOSENTAN**, bosentan 125 mg tablet, 60

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

5619R *Bosentan GH, GQ* – **BOSENTAN**, bosentan 125 mg tablet, 60

5619R *Bosentan Mylan, AF* – **BOSENTAN**, bosentan 125 mg tablet, 60

5619R *Bosentan RBX, RA* – **BOSENTAN**, bosentan 125 mg tablet, 60

5619R *Bosentan Sandoz, SZ* – **BOSENTAN**, bosentan 125 mg tablet, 60

10067W *Renflexis, MK* – **INFLIXIMAB**, infliximab 100 mg injection, 1 vial

10196P *Renflexis, MK* – **INFLIXIMAB**, infliximab 100 mg injection, 1 vial

5753T *Renflexis, MK* – **INFLIXIMAB**, infliximab 100 mg injection, 1 vial

5754W *Renflexis, MK* – **INFLIXIMAB**, infliximab 100 mg injection, 1 vial

5755X *Renflexis, MK* – **INFLIXIMAB**, infliximab 100 mg injection, 1 vial

5756Y *Renflexis, MK* – **INFLIXIMAB**, infliximab 100 mg injection, 1 vial

5757B *Renflexis, MK* – **INFLIXIMAB**, infliximab 100 mg injection, 1 vial

5758C *Renflexis, MK* – **INFLIXIMAB**, infliximab 100 mg injection, 1 vial

9654D *Renflexis, MK* – **INFLIXIMAB**, infliximab 100 mg injection, 1 vial

9569P *Valganciclovir AN, EA* – **VALGANCICLOVIR**, valganciclovir 450 mg tablet, 60

9569P *Valganciclovir Mylan, AF* – **VALGANCICLOVIR**, valganciclovir 450 mg tablet, 60

9569P *Valganciclovir Sandoz, SZ* – **VALGANCICLOVIR**, valganciclovir 450 mg tablet, 60

Addition – Equivalence Indicator

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

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

9569P *Valcyte, RO* – **VALGANCICLOVIR**, valganciclovir 450 mg tablet, 60

Alterations

Alteration – Restriction

The following items have additions, deletions or alterations to restrictions, notes and/or cautions.

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

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

Highly Specialised Drugs Program (Community Access)

Additions

Addition – Item

11142K **TENOFOVIR**, tenofovir disoproxil phosphate 291 mg tablet, 30 *(Tenofovir GH)*

11155D **TENOFOVIR**, tenofovir disoproxil maleate 300 mg tablet, 30 *(Tenofovir Disoproxil Mylan)*

11146P **TENOFOVIR + EMTRICITABINE**, tenofovir disoproxil phosphate 291 mg + emtricitabine 200 mg tablet, 30 *(Tenofovir EMT GH)*

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

Addition – Brand

10306K *Valganciclovir AN, EA* – **VALGANCICLOVIR**, valganciclovir 450 mg tablet, 60

10306K *Valganciclovir Mylan, AF* – **VALGANCICLOVIR**, valganciclovir 450 mg tablet, 60

10306K *Valganciclovir Sandoz, SZ* – **VALGANCICLOVIR**, valganciclovir 450 mg tablet, 60

Addition – Equivalence Indicator

10310P *Viread, GI* – **TENOFOVIR**, tenofovir disoproxil fumarate 300 mg tablet, 30

10347N *Truvada, GI* – **TENOFOVIR + EMTRICITABINE**, tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg tablet, 30

10306K *Valcyte, RO* – **VALGANCICLOVIR**, valganciclovir 450 mg tablet, 60

Alterations

Alteration – Restriction

The following items have additions, deletions or alterations to restrictions, notes and/or cautions.

10310P **TENOFOVIR**, tenofovir disoproxil fumarate 300 mg tablet, 30 *(Viread)*

10347N **TENOFOVIR + EMTRICITABINE**, tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg tablet, 30 *(Truvada)*

Advance Notices

1 September 2017

Deletion – Brand

10311Q *Lamivudine RBX, RA* – **LAMIVUDINE**, lamivudine 300 mg tablet, 30

10348P *Lamivudine RBX, RA* – **LAMIVUDINE**, lamivudine 150 mg tablet, 60

10304H *Nevirapine RBX, RA* – **NEVIRAPINE**, nevirapine 200 mg tablet, 60

IVF Program

Additions

Addition – Item

11154C **HUMAN CHORIONIC GONADOTROPHIN**, human chorionic gonadotrophin 1500 units injection [3 vials] (&) inert substance diluent [3 x 1 mL vials], 1 pack *(Pregnyl)*

11156E **HUMAN CHORIONIC GONADOTROPHIN**, human chorionic gonadotrophin 5000 units injection [1 vial] (&) inert substance diluent [1 mL vial], 1 pack *(Pregnyl)*

Alterations

Alteration – Restriction

The following items have additions, deletions or alterations to restrictions, notes and/or cautions.

6178E **HUMAN CHORIONIC GONADOTROPHIN**, human chorionic gonadotrophin 1500 units injection [3 ampoules] (&) inert substance diluent [3 x 1 mL ampoules], 1 pack *(Pregnyl)*

6181H **HUMAN CHORIONIC GONADOTROPHIN**, human chorionic gonadotrophin 5000 units injection [1 ampoule] (&) inert substance diluent [1 mL ampoule], 1 pack *(Pregnyl)*

Repatriation Pharmaceutical Benefits

Alterations

Alteration – Manufacturer Code

		From	*To*
4089F	*Atrovent Nasal Aqueous* – **IPRATROPIUM**, ipratropium bromide monohydrate 22 microgram/actuation nasal spray, 180 actuations	BY	VZ
4090G	*Atrovent Nasal Forte* – **IPRATROPIUM**, ipratropium bromide monohydrate 44 microgram/actuation nasal spray, 180 actuations	BY	VZ
4584G	*Vasafil 25* – **SILDENAFIL**, sildenafil 25 mg tablet, 4	QA	RW
4585H	*Vasafil 50* – **SILDENAFIL**, sildenafil 50 mg tablet, 4	QA	RW
4586J	*Vasafil 100* – **SILDENAFIL**, sildenafil 100 mg tablet, 4	QA	RW

Advance Notices

1 September 2017

Deletion – Brand

4453J *Mylanta Double Strength, JT* – **ALUMINIUM HYDROXIDE WITH MAGNESIUM HYDROXIDE AND SIMETHICONE**, ALUMINIUM HYDROXIDE with MAGNESIUM HYDROXIDE and SIMETHICONE Tablet 400 mg-400 mg-40 mg, 100

4106D *Stieprox Liquid, GK* – **CICLOPIROX**, ciclopirox olamine 1.5% shampoo, 60 mL

General Pharmaceutical Benefits

▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE

Restricted benefit

Tyrosinaemia

amino acid formula with vitamins and minerals without phenylalanine and tyrosine powder for oral liquid, 30 x 34 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11151X NP	4	5	..	*3888.75	38.80	TYR express 20 [VF]

▪ CRIZOTINIB

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

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

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less.

Population criteria:

- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.

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

(1) a completed authority prescription form; and

(2) a completed ALK-Positive Non-Small-Cell Lung Cancer Authority Application - Supporting Information Form, which includes details of ALK gene rearrangement in tumour material by FISH testing.

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must not have progressive disease.

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

crizotinib 200 mg capsule, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10323H	1	1	..	7277.82	38.80	Xalkori [PF]

crizotinib 250 mg capsule, 60

10322G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	7277.82	38.80	Xalkori [PF]

▪ HUMAN CHORIONIC GONADOTROPHIN

Note Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

Note Pharmaceutical benefits that have the form chorionic gonadotrophin ampoule and chorionic gonadotrophin vial are equivalent for the purposes of substitution.

Restricted benefit

Anovulatory infertility

Note Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomifene citrate and/or gonadorelin and failed to have conceived.

Note Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.

Note Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

Restricted benefit

Infertility

Clinical criteria:

- The condition must be due to hypogonadotrophic hypogonadism.

Population criteria:

- Patient must be male.

Restricted benefit

Infertility

Clinical criteria:

- The condition must be associated with isolated luteinising hormone deficiency.

Population criteria:

- Patient must be male.

Restricted benefit

Combined deficiency of human growth hormone and gonadotrophins

Clinical criteria:

- Patient must be one in whom the absence of secondary sexual characteristics indicates a lag in maturation.

Population criteria:

- Patient must be male.

Restricted benefit

Hypogonadism or delayed puberty

Clinical criteria:

- Patient must show clinical evidence of the condition, **AND**
- The treatment must not extend beyond 6 months.

Population criteria:

- Patient must be male, **AND**
- Patient must be aged 16 years or older.

human chorionic gonadotrophin 1500 units injection [3 ampoules] (&) inert substance diluent [3 x 1 mL ampoules], 1 pack

1581F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	45.04	38.80	Pregnyl [MK]

human chorionic gonadotrophin 1500 units injection [3 vials] (&) inert substance diluent [3 x 1 mL vials], 1 pack

11148R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	45.04	38.80	Pregnyl [MK]

▪ SOFOSBUVIR + VELPATASVIR

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

sofosbuvir 400 mg + velpatasvir 100 mg tablet, 28

11147Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	2	..	22216.19	38.80	Epclusa [GI]

Highly Specialised Drugs Program (Private Hospital)

▪ EPOPROSTENOL

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(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 provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months 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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

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

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change or re-commencement of therapy for all patients)

Clinical criteria:

- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have received prior treatment with a PBS-subsidised PAH agent other than this agent; OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have failed to respond to a prior PBS-subsidised PAH agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and

(4) for WHO Functional Class III patients, where this is the first application for this agent, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

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 provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent 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, as assessed by a physician from a designated hospital.

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, as assessed by a physician from a designated hospital.

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, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months 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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

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

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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 3 months following cessation of therapy.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients) or Initial 2 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

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

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

Clinical criteria:

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

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 provided with the written First Continuing treatment application, 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 provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent 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, as assessed by a physician from a designated hospital.

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, as assessed by a physician from a designated hospital.

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, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

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

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

Clinical criteria:

- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

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

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

epoprostenol 1.5 mg injection, 1 vial

10129D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	77.70	Veletri [AT]

epoprostenol 500 microgram injection, 1 vial

10111E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	43.76	Veletri [AT]

▪ SOFOSBUVIR + VELPATASVIR

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

sofosbuvir 400 mg + velpatasvir 100 mg tablet, 28

11144M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	..	22113.82	Epclusa [GI]

Highly Specialised Drugs Program (Public Hospital)

▪ EPOPROSTENOL

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(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 provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months 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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

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

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change or re-commencement of therapy for all patients)

Clinical criteria:

- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have received prior treatment with a PBS-subsidised PAH agent other than this agent; OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have failed to respond to a prior PBS-subsidised PAH agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and

(4) for WHO Functional Class III patients, where this is the first application for this agent, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

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 provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent 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, as assessed by a physician from a designated hospital.

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, as assessed by a physician from a designated hospital.

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, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months 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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 8 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

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

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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 3 months following cessation of therapy.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients) or Initial 2 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

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

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

Clinical criteria:

- Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

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 provided with the written First Continuing treatment application, 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 provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent 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, as assessed by a physician from a designated hospital.

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, as assessed by a physician from a designated hospital.

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, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

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.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

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

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

Clinical criteria:

- Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR
- Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, **AND**
- Patient must have been assessed by a physician at a designated hospital, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, macitentan, and riociguat.

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

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

epoprostenol 1.5 mg injection, 1 vial

10117L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	66.55	Veletri [AT]

epoprostenol 500 microgram injection, 1 vial

10130E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	33.28	Veletri [AT]

▪ SOFOSBUVIR + VELPATASVIR

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

sofosbuvir 400 mg + velpatasvir 100 mg tablet, 28

11145N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	..	22066.67	Epclusa [GI]

Highly Specialised Drugs Program (Community Access)

▪ TENOFOVIR

Note Pharmaceutical benefits that have the forms tenofovir disoproxil phosphate 291 mg tablet, tenofovir disoproxil maleate 300 mg tablet, and tenofovir disoproxil fumarate 300 mg tablet are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

6998

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

6982

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

6980

Chronic hepatitis B infection

Clinical criteria:

- Patient must have cirrhosis, **AND**
- Patient must be nucleoside analogue naive, **AND**
- Patient must have detectable HBV DNA, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

Note Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

Authority required (STREAMLINED)

6992

Chronic hepatitis B infection

Clinical criteria:

- Patient must not have cirrhosis, **AND**
- Patient must be nucleoside analogue naive, **AND**
- Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR
- Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, **AND**
- Patient must have evidence of chronic liver injury determined by: (i) confirmed elevated serum ALT; or (ii) liver biopsy, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Note Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

Authority required (STREAMLINED)

6983

Chronic hepatitis B infection

Clinical criteria:

- Patient must have cirrhosis, **AND**
- Patient must have failed antihepadnaviral therapy, **AND**
- Patient must have detectable HBV DNA.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

Note Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

Authority required (STREAMLINED)

6984

Chronic hepatitis B infection

Clinical criteria:

- Patient must not have cirrhosis, **AND**
- Patient must have failed antihepadnaviral therapy, **AND**
- Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; OR
- Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance.

Note Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

tenofovir disoproxil fumarate 300 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10310P	2	5	..	*809.03	38.80	[a] Viread [GI]

tenofovir disoproxil maleate 300 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11155D	2	5	..	*809.03	38.80	[a] Tenofovir Disoproxil Mylan [AF]

tenofovir disoproxil phosphate 291 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11142K	2	5	..	*809.03	38.80	[a] Tenofovir GH [GQ]

▪ TENOFOVIR + EMTRICITABINE

Note Pharmaceutical benefits that have the forms tenofovir disoproxil phosphate 291 mg with emtricitabine 200 mg tablet, tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg tablet, and tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg tablet are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

6985

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

6986

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10347N	2	5	..	*1268.25	38.80	[a] Truvada [GI]

tenofovir disoproxil maleate 300 mg + emtricitabine 200 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11149T	2	5	..	*1268.25	38.80	[a] Tenofovir Disoproxil Emtricitabine Mylan 300/200 [AF]

tenofovir disoproxil phosphate 291 mg + emtricitabine 200 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11146P	2	5	..	*1268.25	38.80	[a] Tenofovir EMT GH [GQ]

IVF Treatment Program

▪ HUMAN CHORIONIC GONADOTROPHIN

Note Pharmaceutical benefits that have the form chorionic gonadotrophin ampoule and chorionic gonadotrophin vial are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

6991

Assisted Reproductive Technology

Clinical criteria:

- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

human chorionic gonadotrophin 1500 units injection [3 ampoules] (&) inert substance diluent [3 x 1 mL ampoules], 1 pack

6178E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	41.89	38.80	Pregnyl [MK]

human chorionic gonadotrophin 1500 units injection [3 vials] (&) inert substance diluent [3 x 1 mL vials], 1 pack

11154C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	41.89	38.80	Pregnyl [MK]

human chorionic gonadotrophin 5000 units injection [1 ampoule] (&) inert substance diluent [1 mL ampoule], 1 pack

6181H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	..	..	*27.33	28.54	Pregnyl [MK]

human chorionic gonadotrophin 5000 units injection [1 vial] (&) inert substance diluent [1 mL vial], 1 pack

11156E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	..	..	*27.33	28.54	Pregnyl [MK]