



Australian Government

Department of Health



Schedule of Pharmaceutical Benefits

Summary of Changes

Effective 1 May 2017



Fees, Patient Contributions and Safety Net Thresholds

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

Dispensing Fees:	Ready-prepared	\$7.02
	Dangerous drug fee	\$2.95
	Extemporaneously-prepared	\$9.06
	Allowable additional patient charge*	\$4.38
Additional Fees (for safety net prices):	Ready-prepared	\$1.19
	Extemporaneously-prepared	\$1.55
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 May 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

- 11112W **CHLORAMPHENICOL**, chloramphenicol 0.5% eye drops, 10 mL (*Chlorsig*)
- 11101G **DACLIZUMAB**, daclizumab 150 mg/mL injection, 1 mL injection device (*Zinbryta*)
- 11107N **FOSAPREPITANT**, fosaprepitant 150 mg injection, 1 vial (*Emend IV*)
- 11108P **HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE**, high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate oral semi-solid, 48 x 100 g tubs (*Keyo*)
- 11100F **NINTEDANIB**, nintedanib 100 mg capsule, 60 (*Ofev*)
- 11106M **NINTEDANIB**, nintedanib 150 mg capsule, 60 (*Ofev*)
- 11102H **OXYCODONE + NALOXONE**, oxycodone hydrochloride 60 mg + naloxone hydrochloride 30 mg modified release tablet, 28 (*Targin 60/30*)
- 11111T **OXYCODONE + NALOXONE**, oxycodone hydrochloride 80 mg + naloxone hydrochloride 40 mg modified release tablet, 28 (*Targin 80/40*)
- 11110R **PROTEIN FORMULA WITH CARBOHYDRATE, FAT, VITAMINS AND MINERALS**, protein formula with carbohydrate, fat, vitamins and minerals oral liquid, 8 x 500 mL pouches (*Nutrini Peptisorb Energy*)

Addition – Brand

- 8594H *Amisulpride AN, EA* – **AMISULPRIDE**, amisulpride 100 mg tablet, 30
- 8595J *Amisulpride AN, EA* – **AMISULPRIDE**, amisulpride 200 mg tablet, 60
- 8596K *Amisulpride AN, EA* – **AMISULPRIDE**, amisulpride 400 mg tablet, 60
- 8179L *Arianna 1, AF* – **ANASTROZOLE**, anastrozole 1 mg tablet, 30
- 8179L *Astzul, JU* – **ANASTROZOLE**, anastrozole 1 mg tablet, 30
- 9106G *APO-Doxycycline, TX* – **DOXYCYCLINE**, doxycycline 50 mg tablet, 25
- 10781K *APO-Doxycycline, TX* – **DOXYCYCLINE**, doxycycline 100 mg tablet, 7
- 1800R *APO-Doxycycline, TX* – **DOXYCYCLINE**, doxycycline 100 mg tablet, 21
- 5082L *APO-Doxycycline, TX* – **DOXYCYCLINE**, doxycycline 100 mg tablet, 7 (**Dental**)

9105F	<i>APO-Doxycycline, TX</i> – DOXYCYCLINE , doxycycline 100 mg tablet, 7
9107H	<i>APO-Doxycycline, TX</i> – DOXYCYCLINE , doxycycline 100 mg tablet, 7
1434L	<i>APO-Fluoxetine, TX</i> – FLUOXETINE , fluoxetine 20 mg capsule, 28
2414C	<i>FUROSEMIDE AN, EA</i> – FRUSEMIDE , frusemide 20 mg tablet, 100
2412Y	<i>FUROSEMIDE AN, EA</i> – FRUSEMIDE , frusemide 40 mg tablet, 100
8370M	<i>APO-Naltrexone, TX</i> – NALTREXONE , naltrexone hydrochloride 50 mg tablet, 30
1850J	<i>Phenobarb, RW</i> – PHENOBARBITONE , phenobarbitone 30 mg tablet, 200
2590H	<i>Rosuvastatin generichealth, HQ</i> – ROSUVASTATIN , rosuvastatin 5 mg tablet, 30
2606E	<i>Rosuvastatin generichealth, HQ</i> – ROSUVASTATIN , rosuvastatin 5 mg tablet, 30
3402C	<i>Rosuvastatin generichealth, HQ</i> – ROSUVASTATIN , rosuvastatin 5 mg tablet, 30
9042X	<i>Rosuvastatin generichealth, HQ</i> – ROSUVASTATIN , rosuvastatin 5 mg tablet, 30
2584B	<i>Rosuvastatin generichealth, HQ</i> – ROSUVASTATIN , rosuvastatin 10 mg tablet, 30
2628H	<i>Rosuvastatin generichealth, HQ</i> – ROSUVASTATIN , rosuvastatin 10 mg tablet, 30
3403D	<i>Rosuvastatin generichealth, HQ</i> – ROSUVASTATIN , rosuvastatin 10 mg tablet, 30
9043Y	<i>Rosuvastatin generichealth, HQ</i> – ROSUVASTATIN , rosuvastatin 10 mg tablet, 30
2574L	<i>Rosuvastatin generichealth, HQ</i> – ROSUVASTATIN , rosuvastatin 20 mg tablet, 30
2609H	<i>Rosuvastatin generichealth, HQ</i> – ROSUVASTATIN , rosuvastatin 20 mg tablet, 30
3404E	<i>Rosuvastatin generichealth, HQ</i> – ROSUVASTATIN , rosuvastatin 20 mg tablet, 30
9044B	<i>Rosuvastatin generichealth, HQ</i> – ROSUVASTATIN , rosuvastatin 20 mg tablet, 30
2594M	<i>Rosuvastatin generichealth, HQ</i> – ROSUVASTATIN , rosuvastatin 40 mg tablet, 30
2636R	<i>Rosuvastatin generichealth, HQ</i> – ROSUVASTATIN , rosuvastatin 40 mg tablet, 30
3405F	<i>Rosuvastatin generichealth, HQ</i> – ROSUVASTATIN , rosuvastatin 40 mg tablet, 30
9045C	<i>Rosuvastatin generichealth, HQ</i> – ROSUVASTATIN , rosuvastatin 40 mg tablet, 30
8378Y	<i>Temolide, JU</i> – TEMOZOLOMIDE , temozolomide 5 mg capsule, 5
8819E	<i>Temolide, JU</i> – TEMOZOLOMIDE , temozolomide 5 mg capsule, 5
8379B	<i>Temolide, JU</i> – TEMOZOLOMIDE , temozolomide 20 mg capsule, 5
8820F	<i>Temolide, JU</i> – TEMOZOLOMIDE , temozolomide 20 mg capsule, 5
8380C	<i>Temolide, JU</i> – TEMOZOLOMIDE , temozolomide 100 mg capsule, 5
8821G	<i>Temolide, JU</i> – TEMOZOLOMIDE , temozolomide 100 mg capsule, 5
9361Q	<i>Temolide, JU</i> – TEMOZOLOMIDE , temozolomide 140 mg capsule, 5
9362R	<i>Temolide, JU</i> – TEMOZOLOMIDE , temozolomide 140 mg capsule, 5
10062N	<i>Temolide, JU</i> – TEMOZOLOMIDE , temozolomide 180 mg capsule, 5
2438H	<i>Temolide, JU</i> – TEMOZOLOMIDE , temozolomide 180 mg capsule, 5
8381D	<i>Temolide, JU</i> – TEMOZOLOMIDE , temozolomide 250 mg capsule, 5
2180R	<i>APO-Tranexamic Acid, TX</i> – TRANEXAMIC ACID , tranexamic acid 500 mg tablet, 100

Addition – Equivalence Indicator

2180R	<i>Cyklokapron, PF</i> – TRANEXAMIC ACID , tranexamic acid 500 mg tablet, 100
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Deletions

Deletion – Item

8234J	ACICLOVIR , aciclovir 800 mg tablet, 120 (<i>Acyclo-V 800</i>)
2646G	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN , amino acid formula with vitamins and minerals without lysine and low in tryptophan powder for oral liquid, 500 g (<i>XLYS, LOW TRY Maxamaid</i>)
8328H	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE , amino acid formula with vitamins and minerals without methionine powder for oral liquid, 500 g (<i>XMET Maxamaid</i>)

8059E	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, THREONINE AND VALINE AND LOW IN ISOLEUCINE , amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine powder for oral liquid, 500 g (<i>XMTVI Maxamaid</i>)
8446M	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, 500 g (<i>XPhen, Tyr Maxamaid</i>)
8260R	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE , amino acid formula with vitamins and minerals without valine, leucine and isoleucine powder for oral liquid, 500 g (<i>MSUD Maxamaid</i>)
1140B	BACILLUS CALMETTE AND GUERIN-CONNAUGHT STRAIN , Bacillus Calmette and Guerin-Connaught strain 660 million colony forming units injection [81 mg vial] (&) inert substance diluent [3 mL vial], 1 pack (<i>ImmuCyst</i>)
2419H	CARBAMAZEPINE , carbamazepine 200 mg tablet, 200 (<i>Teril</i>)
5040G	CARBAMAZEPINE , carbamazepine 200 mg tablet, 200 (<i>Teril</i>) (Dental)
8015W	GESTRINONE , gestrinone 2.5 mg capsule, 8 (<i>Dimetriose</i>)
8183Q	INTERFERON ALFA-2A , interferon alfa-2a 6 million units/0.5 mL injection, 0.5 mL syringe (<i>Roferon-A</i>)
8552D	INTERFERON ALFA-2A , interferon alfa-2a 6 million units/0.5 mL injection, 0.5 mL syringe (<i>Roferon-A</i>)
2206D	VERAPAMIL , verapamil hydrochloride 160 mg modified release capsule, 30 (<i>Veracaps SR</i>)
2207E	VERAPAMIL , verapamil hydrochloride 240 mg modified release capsule, 30 (<i>Veracaps SR</i>)

Deletion – Brand

8179L	<i>Arianna, AF</i> – ANASTROZOLE , anastrozole 1 mg tablet, 30
1561E	<i>Chem mart Clomipramine, CH</i> – CLOMIPRAMINE , clomipramine hydrochloride 25 mg tablet, 50
1561E	<i>Terry White Chemists Clomipramine, TW</i> – CLOMIPRAMINE , clomipramine hydrochloride 25 mg tablet, 50
3161J	<i>Ranzepam, RA</i> – DIAZEPAM , diazepam 2 mg tablet, 50
5071X	<i>Ranzepam, RA</i> – DIAZEPAM , diazepam 2 mg tablet, 50 (Dental)
1299J	<i>Chem mart Diclofenac, CH</i> – DICLOFENAC , diclofenac sodium 25 mg enteric tablet, 50
1299J	<i>Terry White Chemists Diclofenac, TW</i> – DICLOFENAC , diclofenac sodium 25 mg enteric tablet, 50
5076E	<i>Chem mart Diclofenac, CH</i> – DICLOFENAC , diclofenac sodium 25 mg enteric tablet, 50 (Dental)
5076E	<i>Terry White Chemists Diclofenac, TW</i> – DICLOFENAC , diclofenac sodium 25 mg enteric tablet, 50 (Dental)
1300K	<i>Chem mart Diclofenac, CH</i> – DICLOFENAC , diclofenac sodium 50 mg enteric tablet, 50
1300K	<i>Terry White Chemists Diclofenac, TW</i> – DICLOFENAC , diclofenac sodium 50 mg enteric tablet, 50
5077F	<i>Chem mart Diclofenac, CH</i> – DICLOFENAC , diclofenac sodium 50 mg enteric tablet, 50 (Dental)
5077F	<i>Terry White Chemists Diclofenac, TW</i> – DICLOFENAC , diclofenac sodium 50 mg enteric tablet, 50 (Dental)
8729K	<i>GRANISETRON APOTEX, TX</i> – GRANISETRON , granisetron 3 mg/3 mL injection, 3 mL ampoule
8730L	<i>GRANISETRON APOTEX, TX</i> – GRANISETRON , granisetron 3 mg/3 mL injection, 3 mL ampoule
8246B	<i>Irbesartan RBX, RA</i> – IRBESARTAN , irbesartan 75 mg tablet, 30
1850J	<i>Phenobarbitone Aspen, RW</i> – PHENOBARBITONE , phenobarbitone 30 mg tablet, 200
1968N	<i>APO-Quinapril, TX</i> – QUINAPRIL , quinapril 5 mg tablet, 30

Deletion – Equivalence Indicator

11068M	<i>Orencia ClickJect, BQ</i> – ABATACEPT , abatacept 125 mg/mL injection, 4 x 1 mL syringes
11092T	<i>Orencia ClickJect, BQ</i> – ABATACEPT , abatacept 125 mg/mL injection, 4 x 1 mL syringes
1220F	<i>Orencia, BQ</i> – ABATACEPT , abatacept 125 mg/mL injection, 4 x 1 mL syringes
1221G	<i>Orencia, BQ</i> – ABATACEPT , abatacept 125 mg/mL injection, 4 x 1 mL syringes

Alterations

Alteration – Item Description

From

10075G **CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE**, betamethasone (as dipropionate) 0.05% + calcipotriol 0.005% gel, 60 g (*Daivobet 50/500 gel*)

To

10075G **CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE**, calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% gel, 60 g (*Daivobet 50/500 gel*)

Alteration – Restriction

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

- 11068M **ABATACEPT**, abatacept 125 mg/mL injection, 4 x 1 mL syringes (*Orencia ClickJect*)
- 11092T **ABATACEPT**, abatacept 125 mg/mL injection, 4 x 1 mL syringes (*Orencia ClickJect*)
- 1220F **ABATACEPT**, abatacept 125 mg/mL injection, 4 x 1 mL syringes (*Orencia*)
- 1221G **ABATACEPT**, abatacept 125 mg/mL injection, 4 x 1 mL syringes (*Orencia*)
- 8465M **BUPROPION**, bupropion hydrochloride 150 mg modified release tablet, 30 (*Zyban*)
- 8710K **BUPROPION**, bupropion hydrochloride 150 mg modified release tablet, 90 (*Zyban*)
- 10075G **CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE**, calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% + calcipotriol 0.005% gel, 60 g (*Daivobet 50/500 gel*)
- 5276Q **CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE**, calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% gel, 30 g (*Daivobet 50/500 gel*)
- 9494Q **CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE**, calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% ointment, 30 g (*Calcipotriol/Betamethasone Sandoz 50/500, Daivobet*)
- 1706T **CARBAMAZEPINE**, CARBAMAZEPINE Tablet 200 mg, 100 (*Carbamazepine Sandoz, Tegretol 200*)
- 1724R **CARBAMAZEPINE**, CARBAMAZEPINE Tablet 200 mg, 100 (*Carbamazepine Sandoz, Tegretol 200*)(**Dental**)
- 2896K **DIMETHYL FUMARATE**, dimethyl fumarate 120 mg enteric capsule, 14 (*Tecfidera*)
- 2943X **DIMETHYL FUMARATE**, dimethyl fumarate 120 mg enteric capsule, 14 (*Tecfidera*)
- 2966D **DIMETHYL FUMARATE**, dimethyl fumarate 240 mg enteric capsule, 56 (*Tecfidera*)
- 5262Y **FINGOLIMOD**, fingolimod 500 microgram capsule, 28 (*Gilenya*)
- 10416F **GLATIRAMER ACETATE**, glatiramer acetate 40 mg/mL injection, 12 x 1 mL syringes (*Copaxone*)
- 8726G **GLATIRAMER ACETATE**, glatiramer acetate 20 mg/mL injection, 28 x 1 mL syringes (*Copaxone*)
- 8403G **INTERFERON BETA-1A**, interferon beta-1a 44 microgram/0.5 mL (12 million units) injection, 12 x 0.5 mL syringes (*Rebif 44*)
- 8805K **INTERFERON BETA-1A**, interferon beta-1a 6 million units (30 microgram)/0.5 mL injection, 4 x 0.5 mL syringes (*Avonex*)
- 8968B **INTERFERON BETA-1A**, INTERFERON BETA-1a Injection 44 micrograms (12,000,000 i.u.) in 0.5 mL single dose autoinjector, 12 (*Rebif 44*)
- 9332E **INTERFERON BETA-1A**, interferon beta-1a 132 microgram/1.5 mL (12 million units) injection, 4 x 1.5 mL cartridges (*Rebif 44*)
- 8101J **INTERFERON BETA-1B**, interferon beta-1b 8 million international units (250 microgram) injection [15 x 250 microgram vials] (&) inert substance diluent [15 x 1.2 mL syringes], 1 pack (*Betaferon*)
- 10731T **NETUPITANT + PALONOSETRON**, netupitant 300 mg + palonosetron 500 microgram capsule, 1 (*Akynzeo*)
- 10076H **NICOTINE**, nicotine 25 mg/16 hours patch, 28 (*nicorette 16hr Invisipatch*)
- 3414Q **NICOTINE**, nicotine 21 mg/24 hours patch, 28 (*Nicotinell Step 1*)
- 5465P **NICOTINE**, nicotine 21 mg/24 hours patch, 28 (*Nicabate P*)
- 5572G **NICOTINE**, nicotine 14 mg/24 hours patch, 28 (*Nicotinell Step 2*)
- 5573H **NICOTINE**, nicotine 7 mg/24 hours patch, 28 (*Nicotinell Step 3*)
- 10220X **PEGINTERFERON BETA-1A**, peginterferon beta-1a 125 microgram/0.5 mL injection, 2 x 0.5 mL injection devices (*Plegridy*)
- 2997R **SALCATONIN**, salcatonin 100 units/mL injection, 5 x 1 mL ampoules (*Miacalcic 100*)
- 2898M **TERIFLUNOMIDE**, teriflunomide 14 mg tablet, 28 (*Aubagio*)

5469W	VARENICLINE , varenicline 1 mg tablet, 56 (<i>Champix</i>)
9128K	VARENICLINE , varenicline 500 microgram tablet [11 tablets] (&) varenicline 1 mg tablet [42 tablets], 53 (<i>Champix</i>)
9129L	VARENICLINE , varenicline 1 mg tablet, 56 (<i>Champix</i>)

Alteration – Restriction Level

5469W	VARENICLINE , varenicline 1 mg tablet, 56 (<i>Champix</i>)	From authority- required	To streamlined
9128K	VARENICLINE , varenicline 500 microgram tablet [11 tablets] (&) varenicline 1 mg tablet [42 tablets], 53 (<i>Champix</i>)	authority- required	streamlined
9129L	VARENICLINE , varenicline 1 mg tablet, 56 (<i>Champix</i>)	authority- required	streamlined

Alteration – Manufacturer Code

		From	To
9192T	<i>Klacid</i> – CLARITHROMYCIN , clarithromycin 250 mg/5 mL powder for oral liquid, 50 mL	AL	GO
8318T	<i>Klacid</i> – CLARITHROMYCIN , clarithromycin 250 mg tablet, 14	AL	GO
8397Y	<i>Teveten</i> – EPROSARTAN , eprosartan 400 mg tablet, 28	AF	GO
8951D	<i>Teveten</i> – EPROSARTAN , eprosartan 400 mg tablet, 28	AF	GO
5491B	<i>Teveten</i> – EPROSARTAN , eprosartan 600 mg tablet, 28	AF	GO
8447N	<i>Teveten</i> – EPROSARTAN , eprosartan 600 mg tablet, 28	AF	GO
8624X	<i>Teveten Plus 600/12.5</i> – EPROSARTAN + HYDROCHLOROTHIAZIDE , eprosartan 600 mg + hydrochlorothiazide 12.5 mg tablet, 28	AF	GO
2361G	<i>Felodur ER 2.5 mg</i> – FELODIPINE , felodipine 2.5 mg modified release tablet, 30	ZA	TX
2361G	<i>Plendil ER</i> – FELODIPINE , felodipine 2.5 mg modified release tablet, 30	AP	GX
2366M	<i>Felodur ER 5 mg</i> – FELODIPINE , felodipine 5 mg modified release tablet, 30	ZA	TX
2366M	<i>Plendil ER</i> – FELODIPINE , felodipine 5 mg modified release tablet, 30	AP	GX
2367N	<i>Felodur ER 10 mg</i> – FELODIPINE , felodipine 10 mg modified release tablet, 30	ZA	TX
2367N	<i>Plendil ER</i> – FELODIPINE , felodipine 10 mg modified release tablet, 30	AP	GX
9022W	<i>Lipidil</i> – FENOFIBRATE , fenofibrate 48 mg tablet, 60	AF	GO
9246P	<i>Lipidil</i> – FENOFIBRATE , fenofibrate 48 mg tablet, 60	AF	GO
9023X	<i>Lipidil</i> – FENOFIBRATE , fenofibrate 145 mg tablet, 30	AF	GO
9247Q	<i>Lipidil</i> – FENOFIBRATE , fenofibrate 145 mg tablet, 30	AF	GO
8512B	<i>Luvox</i> – FLUVOXAMINE , fluvoxamine maleate 50 mg tablet, 30	MQ	GO
8174F	<i>Luvox</i> – FLUVOXAMINE , fluvoxamine maleate 100 mg tablet, 30	MQ	GO
3190X	<i>Brufen</i> – IBUPROFEN , ibuprofen 400 mg tablet, 30	AF	GO
3192B	<i>Brufen</i> – IBUPROFEN , ibuprofen 400 mg tablet, 30	AF	GO
5123P	<i>Brufen</i> – IBUPROFEN , ibuprofen 400 mg tablet, 30 (Dental)	AF	GO
5124Q	<i>Brufen</i> – IBUPROFEN , ibuprofen 400 mg tablet, 30 (Dental)	AF	GO
8534E	<i>Zanidip</i> – LERCANIDIPINE , lercanidipine hydrochloride 10 mg tablet, 28	AL	GO
8679T	<i>Zanidip</i> – LERCANIDIPINE , lercanidipine hydrochloride 20 mg tablet, 28	AL	GO
9144G	<i>Zan-Extra 10/10</i> – LERCANIDIPINE + ENALAPRIL , lercanidipine hydrochloride 10 mg + enalapril maleate 10 mg tablet, 28	AF	GO
9145H	<i>Zan-Extra 10/20</i> – LERCANIDIPINE + ENALAPRIL , lercanidipine hydrochloride 10 mg + enalapril maleate 20 mg tablet, 28	AF	GO
9019Q	<i>Physiotens</i> – MOXONIDINE , moxonidine 200 microgram tablet, 30	AF	GO
9020R	<i>Physiotens</i> – MOXONIDINE , moxonidine 400 microgram tablet, 30	AF	GO
8274L	<i>Zumenon</i> – OESTRADIOL , oestradiol 2 mg tablet, 56	AF	GO
10146B	<i>Femoston 1/10</i> – OESTRADIOL (&) OESTRADIOL + DYDROGESTERONE , oestradiol 1 mg tablet [14] (&) oestradiol 1 mg + dydrogesterone 10 mg tablet [14], 1 pack	AF	GO

8244X	<i>Femoston 2/10</i> – OESTRADIOL (&) OESTRADIOL + DYDROGESTERONE , oestradiol 2 mg tablet [14] (&) oestradiol 2 mg + dydrogesterone 10 mg tablet [14], 1 pack	AF	GO
10142T	<i>Femoston-Conti</i> – OESTRADIOL + DYDROGESTERONE , oestradiol 1 mg + dydrogesterone 5 mg tablet, 28	AF	GO
8020D	<i>Creon 10,000</i> – PANCREATIC EXTRACT , pancreatic extract 10 000 units modified release capsule, 100	AF	GO
9226N	<i>Creon 10,000</i> – PANCREATIC EXTRACT , pancreatic extract 10 000 units modified release capsule, 100	AF	GO
8021E	<i>Creon 25,000</i> – PANCREATIC EXTRACT , pancreatic extract 25 000 units modified release capsule, 100	AF	GO
9227P	<i>Creon 25,000</i> – PANCREATIC EXTRACT , pancreatic extract 25 000 units modified release capsule, 100	AF	GO
9412J	<i>Creon 40,000</i> – PANCREATIC EXTRACT , pancreatic extract 40 000 units modified release capsule, 100	AF	GO
9413K	<i>Creon 40,000</i> – PANCREATIC EXTRACT , pancreatic extract 40 000 units modified release capsule, 100	AF	GO
5453B	<i>Creon Micro</i> – PANCREATIC EXTRACT , pancreatic extract 5000 units/100 mg enteric coated granules, 20 g	AF	GO
5454C	<i>Creon Micro</i> – PANCREATIC EXTRACT , pancreatic extract 5000 units/100 mg enteric coated granules, 20 g	AF	GO
2791X	<i>Gopten</i> – TRANDOLAPRIL , trandolapril 500 microgram capsule, 28	AL	GO
2792Y	<i>Gopten</i> – TRANDOLAPRIL , trandolapril 1 mg capsule, 28	AL	GO
2793B	<i>Gopten</i> – TRANDOLAPRIL , trandolapril 2 mg capsule, 28	AL	GO
8758Y	<i>Gopten</i> – TRANDOLAPRIL , trandolapril 4 mg capsule, 28	AL	GO
9387C	<i>Tarka 2/180</i> – TRANDOLAPRIL + VERAPAMIL , trandolapril 2 mg + verapamil hydrochloride 180 mg modified release tablet, 28	AF	GO
2857J	<i>Tarka 4/240</i> – TRANDOLAPRIL + VERAPAMIL , trandolapril 4 mg + verapamil hydrochloride 240 mg modified release tablet, 28	AF	GO
1250T	<i>Isoptin</i> – VERAPAMIL , verapamil hydrochloride 80 mg tablet, 100	MQ	GO
2208F	<i>Cordilox 180 SR</i> – VERAPAMIL , verapamil hydrochloride 180 mg modified release tablet, 30	AL	GT
2208F	<i>Isoptin 180 SR</i> – VERAPAMIL , verapamil hydrochloride 180 mg modified release tablet, 30	MQ	GO
1241H	<i>Cordilox SR</i> – VERAPAMIL , verapamil hydrochloride 240 mg modified release tablet, 30	AL	GT
1241H	<i>Isoptin SR</i> – VERAPAMIL , verapamil hydrochloride 240 mg modified release tablet, 30	MQ	GO

Alteration – Maximum Quantity

		<i>From</i>	<i>To</i>
10685J	NADROPARIN , nadroparin calcium 3800 anti-Xa international units/0.4 mL injection, 2 x 0.4 mL syringes (<i>Fraxiparine</i>)	2	10
10686K	NADROPARIN , nadroparin calcium 2850 anti-Xa international units/0.3 mL injection, 2 x 0.3 mL syringes (<i>Fraxiparine</i>)	2	10
10687L	NADROPARIN , nadroparin calcium 1900 anti-Xa international units/0.2 mL injection, 2 x 0.2 mL syringes (<i>Fraxiparine</i>)	2	10
10701F	NADROPARIN , nadroparin calcium 2850 anti-Xa international units/0.3 mL injection, 2 x 0.3 mL syringes (<i>Fraxiparine</i>)	2	10
10702G	NADROPARIN , nadroparin calcium 9500 anti-Xa international units/mL injection, 2 x 1 mL syringes (<i>Fraxiparine</i>)	1	5
10706L	NADROPARIN , nadroparin calcium 11 400 anti-Xa international units/0.6 mL injection, 2 x 0.6 mL syringes (<i>Fraxiparine Forte</i>)	1	5
10707M	NADROPARIN , nadroparin calcium 19 000 anti-Xa international units/mL injection, 2 x 1 mL syringes (<i>Fraxiparine Forte</i>)	1	5

10716B	NADROPARIN , nadroparin calcium 5700 anti-Xa international units/0.6 mL injection, 2 x 0.6 mL syringes (<i>Fraxiparine</i>)	2	10
10717C	NADROPARIN , nadroparin calcium 3800 anti-Xa international units/0.4 mL injection, 2 x 0.4 mL syringes (<i>Fraxiparine</i>)	2	10
10718D	NADROPARIN , nadroparin calcium 5700 anti-Xa international units/0.6 mL injection, 2 x 0.6 mL syringes (<i>Fraxiparine</i>)	2	10
10725L	NADROPARIN , nadroparin calcium 15 200 anti-Xa international units/0.8 mL injection, 2 x 0.8 mL syringes (<i>Fraxiparine Forte</i>)	1	5
10733X	NADROPARIN , nadroparin calcium 9500 anti-Xa international units/mL injection, 2 x 1 mL syringes (<i>Fraxiparine</i>)	2	10
10734Y	NADROPARIN , nadroparin calcium 7600 anti-Xa international units/0.8 mL injection, 2 x 0.8 mL syringes (<i>Fraxiparine</i>)	1	5
10735B	NADROPARIN , nadroparin calcium 1900 anti-Xa international units/0.2 mL injection, 2 x 0.2 mL syringes (<i>Fraxiparine</i>)	2	10
10740G	NADROPARIN , nadroparin calcium 7600 anti-Xa international units/0.8 mL injection, 2 x 0.8 mL syringes (<i>Fraxiparine</i>)	2	10

Advance Notices

1 June 2017

Deletion – Brand

1003T	<i>Acyclo-V 200</i> , AF – ACICLOVIR , aciclovir 200 mg tablet, 25
1052J	<i>Acyclo-V 800</i> , AF – ACICLOVIR , aciclovir 800 mg tablet, 35
9012H	<i>Alendrobell plus D3</i> , GQ – ALENDRONATE + COLECALCIFEROL , alendronate 70 mg + colecalciferol 70 microgram tablet, 4
9183H	<i>Alendrobell plus D3</i> , GQ – ALENDRONATE + COLECALCIFEROL , alendronate 70 mg + colecalciferol 140 microgram tablet, 4
2132F	<i>GenRx Alprazolam</i> , GX – ALPRAZOLAM , alprazolam 1 mg tablet, 50
9315G	<i>Candesartan HCTZ RBX 32/25</i> , RA – CANDESARTAN + HYDROCHLOROTHIAZIDE , candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30
1224K	<i>Colestid</i> , PF – COLESTIPOL HYDROCHLORIDE , colestipol hydrochloride 5 g granules, 120 sachets
9250W	<i>Colestid</i> , PF – COLESTIPOL HYDROCHLORIDE , colestipol hydrochloride 5 g granules, 120 sachets
9155W	<i>Duloxetine Sandoz</i> , HX – DULOXETINE , duloxetine 30 mg enteric capsule, 28
9156X	<i>Duloxetine Sandoz</i> , HX – DULOXETINE , duloxetine 60 mg enteric capsule, 28
2487X	<i>Pamacid 20</i> , AF – FAMOTIDINE , famotidine 20 mg tablet, 60
2488Y	<i>Pamacid 40</i> , AF – FAMOTIDINE , famotidine 40 mg tablet, 30
1001Q	<i>Modecate</i> , BQ – FLUPHENAZINE DECANOATE , fluphenazine decanoate 50 mg/2 mL injection, 5 x 2 mL ampoules
1046C	<i>Modecate</i> , BQ – FLUPHENAZINE DECANOATE , fluphenazine decanoate 12.5 mg/0.5 mL injection, 5 x 0.5 mL ampoules
3098C	<i>Modecate</i> , BQ – FLUPHENAZINE DECANOATE , fluphenazine decanoate 25 mg/mL injection, 5 x 1 mL ampoules
8689H	<i>Avandia</i> , GK – ROSIGLITAZONE , rosiglitazone 4 mg tablet, 28
8690J	<i>Avandia</i> , GK – ROSIGLITAZONE , rosiglitazone 8 mg tablet, 28
1973W	<i>Selgene</i> , AF – SELEGILINE , selegiline hydrochloride 5 mg tablet, 100

1 July 2017

Deletion – Brand

8296P	<i>Candesartan GH</i> , GQ – CANDESARTAN , candesartan cilexetil 8 mg tablet, 30
8257N	<i>Carvedilol generichealth</i> , GQ – CARVEDILOL , carvedilol 12.5 mg tablet, 60
8258P	<i>Carvedilol generichealth</i> , GQ – CARVEDILOL , carvedilol 25 mg tablet, 60

1 August 2017

Deletion – Brand

- 8256M *Carvedilol generichealth, GQ* – **CARVEDILOL**, carvedilol 6.25 mg tablet, 60
- 8422G *Dilaudid-HP, MF* – **HYDROMORPHONE**, hydromorphone hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules

1 September 2017

Deletion – Brand

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

1 October 2017

Deletion – Brand

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

1 November 2017

Deletion – Brand

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

Palliative Care

Deletions

Deletion – Brand

- 5355W *Ranzepam, RA* – **DIAZEPAM**, diazepam 2 mg tablet, 50
- 5361E *Chem mart Diclofenac, CH* – **DICLOFENAC**, diclofenac sodium 25 mg enteric tablet, 50
- 5361E *Terry White Chemists Diclofenac, TW* – **DICLOFENAC**, diclofenac sodium 25 mg enteric tablet, 50
- 5362F *Chem mart Diclofenac, CH* – **DICLOFENAC**, diclofenac sodium 50 mg enteric tablet, 50
- 5362F *Terry White Chemists Diclofenac, TW* – **DICLOFENAC**, diclofenac sodium 50 mg enteric tablet, 50

Alterations

Alteration – Manufacturer Code

- | | | From | To |
|-------|--|------|----|
| 5368M | <i>Brufen</i> – IBUPROFEN , ibuprofen 400 mg tablet, 30 | AF | GO |

Highly Specialised Drugs Program (Private Hospital)

Additions

Addition – Item

- 11097C **IVACAFTOR**, ivacaftor 50 mg granules, 4 x 14 sachets (*Kalydeco*)
- 11109Q **IVACAFTOR**, ivacaftor 75 mg granules, 4 x 14 sachets (*Kalydeco*)

Deletions

Deletion – Item

- 2435E **BOCEPREVIR**, boceprevir 200 mg capsule, 336 (*Victrelis*)
- 6212Y **INTERFERON ALFA-2A**, interferon alfa-2a 6 million units/0.5 mL injection, 0.5 mL syringe (*Roferon-A*)

Alterations

Alteration – Restriction

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

- 10243D **ALEMTUZUMAB**, alemtuzumab 12 mg/1.2 mL injection, 1.2 mL vial (*Lemtrada*)
- 10246G **ALEMTUZUMAB**, alemtuzumab 12 mg/1.2 mL injection, 1.2 mL vial (*Lemtrada*)
- 10175M **IVACAFTOR**, ivacaftor 150 mg tablet, 56 (*Kalydeco*)
- 9744W **LEVODOPA + CARBIDOPA ANHYDROUS**, levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL (*Duodopa*)
- 9624M **NATALIZUMAB**, natalizumab 300 mg/15 mL injection, 15 mL vial (*Tysabri*)

Advance Notices

1 June 2017

Deletion – Brand

- 6400W *Pegatron, MK* – **PEGINTERFERON ALFA-2B (&) RIBAVIRIN**, peginterferon alfa-2b 50 microgram injection [4 x 50

	microgram cartridges] (&) ribavirin 200 mg capsule [112 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack
6401X	<i>Pegatron, MK</i> – PEGINTERFERON ALFA-2B (&) RIBAVIRIN , peginterferon alfa-2b 80 microgram injection [4 x 80 microgram cartridges] (&) ribavirin 200 mg capsule [84 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack
6402Y	<i>Pegatron, MK</i> – PEGINTERFERON ALFA-2B (&) RIBAVIRIN , peginterferon alfa-2b 80 microgram injection [4 x 80 microgram cartridges] (&) ribavirin 200 mg capsule [140 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack
6405D	<i>Pegatron, MK</i> – PEGINTERFERON ALFA-2B (&) RIBAVIRIN , peginterferon alfa-2b 100 microgram injection [4 x 100 microgram cartridges] (&) ribavirin 200 mg capsule [112 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack
6407F	<i>Pegatron, MK</i> – PEGINTERFERON ALFA-2B (&) RIBAVIRIN , peginterferon alfa-2b 120 microgram injection [4 x 120 microgram cartridges] (&) ribavirin 200 mg capsule [140 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack
6409H	<i>Pegatron, MK</i> – PEGINTERFERON ALFA-2B (&) RIBAVIRIN , peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (&) ribavirin 200 mg capsule [140 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack
6410J	<i>Pegatron, MK</i> – PEGINTERFERON ALFA-2B (&) RIBAVIRIN , peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (&) ribavirin 200 mg capsule [168 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack
9634C	<i>Pegatron, MK</i> – PEGINTERFERON ALFA-2B (&) RIBAVIRIN , peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (&) ribavirin 200 mg capsule [196 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack

1 July 2017

Deletion – Brand

5036C	<i>Flolan Kit, GK</i> – EPOPROSTENOL , EPOPROSTENOL SODIUM Powder for I.V. infusion 500 micrograms (base) infusion administration set, 1
5042J	<i>Flolan Kit, GK</i> – EPOPROSTENOL , EPOPROSTENOL SODIUM Powder for I.V. infusion 1.5 mg (base) infusion administration set, 1

Highly Specialised Drugs Program (Public Hospital)

Additions

Addition – Item

11105L	IVACFTOR , ivacaftor 50 mg granules, 4 x 14 sachets (<i>Kalydeco</i>)
11098D	IVACFTOR , ivacaftor 75 mg granules, 4 x 14 sachets (<i>Kalydeco</i>)

Deletions

Deletion – Item

2433C	BOCEPREVIR , boceprevir 200 mg capsule, 336 (<i>Victrelis</i>)
5761F	INTERFERON ALFA-2A , interferon alfa-2a 6 million units/0.5 mL injection, 0.5 mL syringe (<i>Roferon-A</i>)

Alterations

Alteration – Restriction

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

10228H	ALEMTUZUMAB , alemtuzumab 12 mg/1.2 mL injection, 1.2 mL vial (<i>Lemtrada</i>)
10232M	ALEMTUZUMAB , alemtuzumab 12 mg/1.2 mL injection, 1.2 mL vial (<i>Lemtrada</i>)
10170G	IVACFTOR , ivacaftor 150 mg tablet, 56 (<i>Kalydeco</i>)
9743T	LEVODOPA + CARBIDOPA ANHYDROUS , levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL (<i>Duodopa</i>)
9505G	NATALIZUMAB , natalizumab 300 mg/15 mL injection, 15 mL vial (<i>Tysabri</i>)

Advance Notices

1 June 2017

Deletion – Brand

9529M	<i>Pegatron, MK</i> – PEGINTERFERON ALFA-2B (&) RIBAVIRIN , peginterferon alfa-2b 50 microgram injection [4 x 50 microgram cartridges] (&) ribavirin 200 mg capsule [112 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack
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9530N	<i>Pegatron, MK</i> – PEGINTERFERON ALFA-2B (&) RIBAVIRIN , peginterferon alfa-2b 80 microgram injection [4 x 80 microgram cartridges] (&) ribavirin 200 mg capsule [84 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack
9531P	<i>Pegatron, MK</i> – PEGINTERFERON ALFA-2B (&) RIBAVIRIN , peginterferon alfa-2b 80 microgram injection [4 x 80 microgram cartridges] (&) ribavirin 200 mg capsule [140 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack
9534T	<i>Pegatron, MK</i> – PEGINTERFERON ALFA-2B (&) RIBAVIRIN , peginterferon alfa-2b 100 microgram injection [4 x 100 microgram cartridges] (&) ribavirin 200 mg capsule [112 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack
9536X	<i>Pegatron, MK</i> – PEGINTERFERON ALFA-2B (&) RIBAVIRIN , peginterferon alfa-2b 120 microgram injection [4 x 120 microgram cartridges] (&) ribavirin 200 mg capsule [140 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack
9538B	<i>Pegatron, MK</i> – PEGINTERFERON ALFA-2B (&) RIBAVIRIN , peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (&) ribavirin 200 mg capsule [140 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack
9539C	<i>Pegatron, MK</i> – PEGINTERFERON ALFA-2B (&) RIBAVIRIN , peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (&) ribavirin 200 mg capsule [168 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack
9540D	<i>Pegatron, MK</i> – PEGINTERFERON ALFA-2B (&) RIBAVIRIN , peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (&) ribavirin 200 mg capsule [196 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack

1 July 2017

Deletion – Brand

5030R	<i>Flolan Kit, GK</i> – EPOPROSTENOL , EPOPROSTENOL SODIUM Powder for I.V. infusion 500 micrograms (base) infusion administration set, 1
5035B	<i>Flolan Kit, GK</i> – EPOPROSTENOL , EPOPROSTENOL SODIUM Powder for I.V. infusion 1.5 mg (base) infusion administration set, 1

Highly Specialised Drugs Program (Community Access)

Additions

Addition – Item

11104K	EMTRICITABINE + RILPIVIRINE + TENOFOVIR ALAFENAMIDE , emtricitabine 200 mg + rilpivirine 25 mg + tenofovir alafenamide 25 mg tablet, 30 tablets (<i>Odefsey</i>)
11099E	EMTRICITABINE + TENOFOVIR ALAFENAMIDE , emtricitabine 200 mg + tenofovir alafenamide 10 mg tablet, 30 (<i>Descovy</i>)
11113X	EMTRICITABINE + TENOFOVIR ALAFENAMIDE , emtricitabine 200 mg + tenofovir alafenamide 25 mg tablet, 30 (<i>Descovy</i>)
11114Y	TENOFOVIR ALAFENAMIDE + EMTRICITABINE + ELVITEGRAVIR + COBICISTAT , tenofovir alafenamide 10 mg + emtricitabine 200 mg + elvitegravir 150 mg + cobicistat 150 mg tablet, 30 (<i>Genvoya</i>)

Addition – Brand

10303G	<i>Nevirapine XR APOTEX, TX</i> – NEVIRAPINE , nevirapine 400 mg modified release tablet, 30
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Addition – Equivalence Indicator

10303G	<i>Viramune XR, BY</i> – NEVIRAPINE , nevirapine 400 mg modified release tablet, 30
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Deletions

Deletion – Item

10354Y	INTERFERON ALFA-2A , interferon alfa-2a 6 million units/0.5 mL injection, 0.5 mL syringe (<i>Roferon-A</i>)
10946D	TENOFOVIR + EMTRICITABINE , tenofovir alafenamide 10mg + emtricitabine 200 mg tablet, 30 (<i>Descovy 10/200</i>)
10966E	TENOFOVIR + EMTRICITABINE , tenofovir alafenamide 25mg + emtricitabine 200 mg tablet, 30 (<i>Descovy 25/200</i>)
10680D	TENOFOVIR + EMTRICITABINE + ELVITEGRAVIR + COBICISTAT , tenofovir alafenamide 10 mg + emtricitabine 200 mg + elvitegravir 150 mg + cobicistat 150 mg tablet, 30 (<i>Genvoya</i>)

Repatriation Pharmaceutical Benefits

Deletions

Deletion – Brand

- 4233T *Finasteride RBX, RA* – **FINASTERIDE**, finasteride 5 mg tablet, 30
- 4325P *Vermox, IA* – **MEBENDAZOLE**, mebendazole 100 mg tablet, 6
- 4462W *Microlax, JT* – **SORBITOL + CITRIC ACID + LAURYL SULFOACETATE SODIUM**, sorbitol 3.125 g/5 mL + citrate sodium dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 4 x 5 mL

Deletion – Equivalence Indicator

- 4325P *Pharmacy Action Worm Treatment, GQ* – **MEBENDAZOLE**, mebendazole 100 mg tablet, 6

Advance Notices

1 June 2017

Deletion – Brand

- 2194L *Alendrobell plus D3, GQ* – **ALENDRONATE + COLECALCIFEROL**, alendronate 70 mg + colecalciferol 70 microgram tablet, 4
- 2224C *Alendrobell plus D3, GQ* – **ALENDRONATE + COLECALCIFEROL**, alendronate 70 mg + colecalciferol 140 microgram tablet, 4

General Pharmaceutical Benefits

▪ ABATACEPT

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

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

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

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

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 TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term

bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alpha antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient

will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

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

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

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested 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 application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

abatacept 125 mg/mL injection, 4 x 1 mL syringes

11068M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	952.70	38.80	Orencia ClickJect [BQ]

abatacept 125 mg/mL injection, 4 x 1 mL syringes

1221G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	952.70	38.80	Orencia [BQ]

■ ABATACEPT**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

- Patient must have severe active rheumatoid arthritis, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
- Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialed, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

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

- (1) completed authority prescription forms; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats.

Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

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

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

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

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;

(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;

(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

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 TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

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

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

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

Clinical criteria:

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

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

(a) completed authority prescription forms; and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

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

Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats.

Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

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

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

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 TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

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

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

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR

- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested 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 application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

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

abatacept 125 mg/mL injection, 4 x 1 mL syringes

11092T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	952.70	38.80	Orencia ClickJect [BQ]

abatacept 125 mg/mL injection, 4 x 1 mL syringes

1220F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	952.70	38.80	Orencia [BQ]

■ BUPROPION

Note Clinical review is recommended within 2 to 3 weeks of the original prescription being requested.

Note The period between commencing a course of bupropion hydrochloride and varenicline tartrate must be at least 6 months.

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

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

Authority required (STREAMLINED)

6881

Nicotine dependence

Treatment Phase: Completion of a short-term (9 weeks) course of treatment

Clinical criteria:

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug during this current course of treatment, **AND**
- Patient must not receive more than 9 weeks of PBS-subsidised treatment with this drug per 12-month period.

Treatment criteria:

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.

bupropion hydrochloride 150 mg modified release tablet, 90

8710K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	164.87	38.80	Zyban [AS]

■ BUPROPION

Note Clinical review is recommended within 2 to 3 weeks of the original prescription being requested.

Note The period between commencing a course of bupropion hydrochloride and varenicline tartrate must be at least 6 months.

Note A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.

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

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

Authority required (STREAMLINED)

6882

Nicotine dependence

Treatment Phase: Commencement of a short-term (9 weeks) course of treatment

Clinical criteria:

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have indicated they are ready to cease smoking, **AND**
- Patient must not receive more than 9 weeks of PBS-subsidised treatment with this drug per 12-month period.

Treatment criteria:

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

bupropion hydrochloride 150 mg modified release tablet, 30

8465M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	62.00	38.80	Zyban [AS]

■ CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE

Note Continuing Therapy Only:

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

Authority required (STREAMLINED)

6873

Chronic stable plaque type psoriasis vulgaris

Clinical criteria:

- The condition must be inadequately controlled by potent topical corticosteroid monotherapy, **AND**
- Patient must require more than 30 grams of product per month.

calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% gel, 60 g

10075G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	1	..	62.58	38.80	Daivobet 50/500 gel [LO]

■ CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE

Note Continuing Therapy Only:

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

Restricted benefit

Chronic stable plaque type psoriasis vulgaris

Clinical criteria:

- The condition must be inadequately controlled by potent topical corticosteroid monotherapy.

calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% gel, 30 g

5276Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	1	..	36.57	37.76	Daivobet 50/500 gel [LO]

calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% ointment, 30 g

9494Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±1	1	..	36.57	37.76	^a Calcipotriol/Betamethasone Sandoz 50/500 [SZ]	^a Daivobet [LO]

■ CARBAMAZEPINE

CARBAMAZEPINE Tablet 200 mg, 100

1724R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	2	..	..	*30.20	31.39	^a Carbamazepine Sandoz [SZ]
			^b 2.96	*33.16	31.39	^a Tegretol 200 [NV]

■ CARBAMAZEPINE

Note Continuing Therapy Only:

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

CARBAMAZEPINE Tablet 200 mg, 100

1706T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*30.20	31.39	^a Carbamazepine Sandoz [SZ]
			^b 2.96	*33.16	31.39	^a Tegretol 200 [NV]

■ CHLORAMPHENICOL

Restricted benefit

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

chloramphenicol 0.5% eye drops, 10 mL

11112W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
MW NP OP	±1	2	..	14.54	15.73	Chlorsig [QA]

■ DACLIZUMAB

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

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Treatment criteria:

- Must be treated by a neurologist.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

Patients should undergo monthly liver function testing while being treated with this drug.

Authority required

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

Treatment criteria:

- Must be treated by a neurologist.

Patients should undergo monthly liver function testing while being treated with this drug.

Authority required

Multiple sclerosis

Treatment Phase: Grandfathering treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years prior to initiation of this drug, **AND**
- Patient must have received treatment with this drug for this condition prior to 1 May 2017, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support), **AND**
- The treatment must not exceed 24 weeks under this restriction.

Treatment criteria:

- Must be treated by a neurologist.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

Patients should undergo monthly liver function testing while being treated with this drug.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

daclizumab 150 mg/mL injection, 1 mL injection device

11101G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	2231.21	38.80	Zinbryta [BD]

■ DIMETHYL FUMARATE

Note Special Pricing Arrangements apply.

Authority required

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have been receiving treatment with this drug prior to 1 December 2013, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

dimethyl fumarate 120 mg enteric capsule, 14

2943X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	486.48	38.80	Tecfidera [BD]

■ DIMETHYL FUMARATE

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

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

dimethyl fumarate 120 mg enteric capsule, 14

2896K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	486.48	38.80	Tecfidera [BD]

■ DIMETHYL FUMARATE

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

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have been receiving treatment with this drug prior to 1 December 2013, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

dimethyl fumarate 240 mg enteric capsule, 56

2966D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1870.61	38.80	Tecfidera [BD]

■ FINGOLIMOD

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

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, **AND**

- Patient must be ambulatory (without assistance or support).
- Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

Authority required

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

fingolimod 500 microgram capsule, 28

5262Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	2206.17	38.80	Gilenya [NV]

▪ **FOSAPREPITANT**

Note This medicine is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy.

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

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

Authority required (STREAMLINED)

6886

Nausea and vomiting

Clinical criteria:

- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy, **AND**
- The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone, **AND**
- Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following agents: altretamine; carmustine; cisplatin when a single dose constitutes a cycle of chemotherapy; cyclophosphamide at a dose of 1500 mg per square metre per day or greater; dacarbazine; procarbazine when a single dose constitutes a cycle of chemotherapy; streptozocin.

No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy.

Authority required (STREAMLINED)

6891

Nausea and vomiting

Clinical criteria:

- The condition must be associated with cytotoxic chemotherapy being used to treat breast cancer, **AND**
- The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone, **AND**
- Patient must be scheduled to be co-administered cyclophosphamide and an anthracycline.

No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy.

Authority required (STREAMLINED)

6887

Nausea and vomiting

Clinical criteria:

- The condition must be associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy, **AND**
- The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle, **AND**
- Patient must have had a prior episode of chemotherapy induced nausea or vomiting, **AND**
- Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following intravenous chemotherapy agents: arsenic trioxide; azacitidine; cyclophosphamide at a dose of less than 1500 mg per square metre per day; cytarabine at a dose of greater than 1 g per square metre per day; dactinomycin; daunorubicin; doxorubicin; epirubicin; fotemustine; idarubicin; ifosfamide; irinotecan; melphalan; methotrexate at a dose of 250 mg to 1 g per square metre; raltitrexed.

No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy.

Concomitant use of a 5HT3 antagonist should not occur with fosaprepitant on days 2 and 3 of any chemotherapy cycle.

Authority required (STREAMLINED)

6852

Nausea and vomiting

Clinical criteria:

- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy, **AND**
 - The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle, **AND**
 - Patient must be scheduled to be administered a chemotherapy regimen that includes either carboplatin or oxaliplatin.
- No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy.

Concomitant use of a 5HT3 antagonist should not occur with fosaprepitant on days 2 and 3 of any chemotherapy cycle.

fosaprepitant 150 mg injection, 1 vial

11107N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	115.03	38.80	Emend IV [MK]

■ GLATIRAMER ACETATE

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

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

Authority required (STREAMLINED)**4881**

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

Authority required (STREAMLINED)**6860**

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

glatiramer acetate 20 mg/mL injection, 28 x 1 mL syringes

8726G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1034.50	38.80	Copaxone [TB]

glatiramer acetate 40 mg/mL injection, 12 x 1 mL syringes

10416F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1034.50	38.80	Copaxone [TB]

■ HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

Note Authorities for increased maximum quantities, up to a maximum of 11, may be authorised.

Restricted benefit

Ketogenic diet

Clinical criteria:

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

Keyo should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate oral semi-solid, 48 x 100 g tubs

11108P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	..	*865.53	38.80	Keyo [VF]

■ INTERFERON BETA-1A

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

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

Authority required (STREAMLINED)**4881**

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

Authority required (STREAMLINED)

6860

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

INTERFERON BETA-1a Injection 44 micrograms (12,000,000 i.u.) in 0.5 mL single dose autoinjector, 12

8968B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	998.03	38.80	Rebif 44 [SG]

interferon beta-1a 132 microgram/1.5 mL (12 million units) injection, 4 x 1.5 mL cartridges

9332E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	998.03	38.80	Rebif 44 [SG]

interferon beta-1a 44 microgram/0.5 mL (12 million units) injection, 12 x 0.5 mL syringes

8403G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	998.03	38.80	Rebif 44 [SG]

interferon beta-1a 6 million units (30 microgram)/0.5 mL injection, 4 x 0.5 mL syringes

8805K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	998.03	38.80	Avonex [BD]

▪ **INTERFERON BETA-1B**

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

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

Authority required (STREAMLINED)

4881

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

Authority required (STREAMLINED)

6860

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

interferon beta-1b 8 million international units (250 microgram) injection [15 x 250 microgram vials] (&) inert substance diluent [15 x 1.2 mL syringes], 1 pack

8101J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	993.86	38.80	Betaferon [BN]

▪ NETUPITANT + PALONOSETRON

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

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

Note This medicine is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy.

Authority required (STREAMLINED)

5991

Nausea and vomiting

Clinical criteria:

- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy, **AND**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following agents: altretamine; carmustine; cisplatin when a single dose constitutes a cycle of chemotherapy; cyclophosphamide at a dose of 1500 mg per square metre per day or greater; dacarbazine; procarbazine when a single dose constitutes a cycle of chemotherapy; streptozocin.

No more than 1 capsule of 300 mg netupitant/0.5 mg palonosetron fixed dose combination will be authorised per cycle of cytotoxic chemotherapy.

Authority required (STREAMLINED)

5994

Nausea and vomiting

Clinical criteria:

- The condition must be associated with cytotoxic chemotherapy being used to treat breast cancer, **AND**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must be scheduled to be co-administered cyclophosphamide and an anthracycline.

No more than 1 capsule of 300 mg netupitant/0.5 mg palonosetron fixed dose combination will be authorised per cycle of cytotoxic chemotherapy.

Authority required (STREAMLINED)

6879

Nausea and vomiting

Clinical criteria:

- The condition must be associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy, **AND**
 - The treatment must be in combination with dexamethasone on day 1 of a chemotherapy cycle, **AND**
 - Patient must be scheduled to be administered a chemotherapy regimen that includes either carboplatin or oxaliplatin.
- No more than 1 capsule of 300 mg netupitant/0.5 mg palonosetron fixed dose combination will be authorised per cycle of cytotoxic chemotherapy.

netupitant 300 mg + palonosetron 500 microgram capsule, 1

10731T

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
±1	5	..	115.03	38.80	Akynzeo [MF]

▪ NICOTINE

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

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

Restricted benefit

Nicotine dependence

Clinical criteria:

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have indicated they are ready to cease smoking, **AND**
- Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.

Treatment criteria:

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

nicotine 14 mg/24 hours patch, 28

5572G

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	2	..	52.64	38.80	Nicotinell Step 2 [ON]

nicotine 21 mg/24 hours patch, 28

3414Q

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	2	..	52.64	38.80	Nicotinell Step 1 [ON]

nicotine 7 mg/24 hours patch, 28

5573H

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	2	..	52.64	38.80	Nicotinell Step 3 [ON]

■ NICOTINE

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

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

Restricted benefit

Nicotine dependence

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition.

Population criteria:

- Patient must be an Aboriginal or a Torres Strait Islander person.

Note Only 2 courses of PBS-subsidised nicotine replacement therapy may be prescribed per 12-month period.

Benefit is improved if used in conjunction with a comprehensive support and counselling program.

Restricted benefit

Nicotine dependence

Clinical criteria:

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have indicated they are ready to cease smoking, **AND**
- Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.

Treatment criteria:

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

nicotine 21 mg/24 hours patch, 28

5465P

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	2	..	52.64	38.80	Nicabate P [GC]

nicotine 25 mg/16 hours patch, 28

10076H

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	2	..	52.64	38.80	nicorette 16hr Invisipatch [JT]

■ NINTEDANIB

Note Special Pricing Arrangements apply.

Note No applications for increased maximum quantities will be authorised.

Note No applications for increased repeats will be authorised.

Authority required

Idiopathic pulmonary fibrosis

Treatment Phase: Initial treatment 1 - new patient

Clinical criteria:

- The condition must be diagnosed through a multidisciplinary team, **AND**
- Patient must have chest high resolution computed tomography (HRCT) consistent with diagnosis of idiopathic pulmonary fibrosis within the previous 12 months, **AND**
- Patient must have a forced vital capacity (FVC) greater than or equal to 50% predicted for age, gender and height, **AND**
- Patient must have a forced expiratory volume in 1 second to forced vital capacity ratio (FEV1/FVC) greater than 0.7, **AND**
- Patient must have diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin equal to or greater than 30%, **AND**
- Patient must not have interstitial lung disease due to other known causes including domestic and occupational environmental exposures, connective tissue disease, or drug toxicity.

Treatment criteria:

- Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.

A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and, where histological material is considered, a pathologist. If attendance is not possible, because of geographical isolation consultation with a multidisciplinary team is required for diagnosis.

Application for authorisation for initial treatment must be in writing and must include:

1. A completed authority prescription form
2. A completed IPF Authority Application Supporting Information Form; and
3. A signed patient acknowledgement.
Patient must have not have an acute respiratory infection at the time of FVC testing.

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

Idiopathic pulmonary fibrosis
Treatment Phase: Continuing treatment

Clinical criteria:

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

Treatment criteria:

- Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.

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).

Authority required

Idiopathic pulmonary fibrosis
Treatment Phase: Initial treatment 2 - Grandfathering treatment

Clinical criteria:

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2017, **AND**
- The condition must have been diagnosed through a multidisciplinary team, **AND**
- Patient must have had a forced vital capacity (FVC) greater than or equal to 50% predicted for age, gender and height at the time treatment with this drug for this condition was initiated, **AND**
- Patient must have had a forced expiratory volume in 1 second (FEV1)/FVC ratio greater than 0.7 at the time treatment with this drug for this condition was initiated, **AND**
- Patient must have had diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin equal to or greater than 30% at the time treatment with this drug for this condition was initiated, **AND**
- Patient must not have interstitial lung disease due to other known causes including domestic and occupational environmental exposures, connective tissue disease, and drug toxicity.

Treatment criteria:

- Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.

A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Application for of initial treatment authorisation must be in writing and must include:

1. A completed authority prescription form
 2. A completed IPF Authority Application Supporting Information Form; and
 3. A signed patient acknowledgement.
- Patient must have not have an acute respiratory infection at the time of FVC testing.

Note Any queries concerning the arrangements to prescribe this drug 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

Written applications for authority to prescribe this drug should be forwarded to:

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

nintedanib 100 mg capsule, 60

11100F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1752.11	38.80	Ofev [BY]

nintedanib 150 mg capsule, 60

11106M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3385.48	38.80	Ofev [BY]

■ OXYCODONE + NALOXONE

Caution The risk of drug dependence is high.

Note Authorities for increased maximum quantities and/or repeats will be granted only for:

- (i) chronic severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic

treatment is less than 12 months; or
 (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
 (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Note Shared Care Model:

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

Restricted benefit

Chronic severe disabling pain

Clinical criteria:

- The condition must be unresponsive to non-opioid analgesics.

oxycodone hydrochloride 60 mg + naloxone hydrochloride 30 mg modified release tablet, 28

11102H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	79.13	38.80	Targin 60/30 [MF]

oxycodone hydrochloride 80 mg + naloxone hydrochloride 40 mg modified release tablet, 28

11111T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	93.77	38.80	Targin 80/40 [MF]

▪ **PEGINTERFERON BETA-1A**

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

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

Authority required (STREAMLINED)

6860

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

peginterferon beta-1a 125 microgram/0.5 mL injection, 2 x 0.5 mL injection devices

10220X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1049.56	38.80	Plegridy [BD]

▪ **PROTEIN FORMULA WITH CARBOHYDRATE, FAT, VITAMINS AND MINERALS**

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

Note Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

Restricted benefit

Dietary management of conditions requiring a source of medium chain triglycerides

Clinical criteria:

- Patient must have fat malabsorption due to liver disease; OR
- Patient must have fat malabsorption due to short gut syndrome; OR
- Patient must have fat malabsorption due to cystic fibrosis; OR
- Patient must have fat malabsorption due to gastrointestinal disorders.

Population criteria:

- Patient must be aged from 1 to 10 years inclusive.

protein formula with carbohydrate, fat, vitamins and minerals oral liquid, 8 x 500 mL pouches

11110R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	10	5	..	*1502.12	38.80	Nutrini Peptisorb Energy [NU]

▪ **SALCATONIN**

Note Continuing Therapy Only:

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

Restricted benefit

Symptomatic Paget disease of bone

Restricted benefit

Hypercalcaemia

Clinical criteria:

- The treatment must be initiated in a hospital.

salcatonin 100 units/mL injection, 5 x 1 mL ampoules

2997R

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
3	5	..	*144.15	38.80	Miacalcic 100 [NV]

■ TERIFLUNOMIDE

Caution Teriflunomide is a category X drug and must not be given to pregnant women or women of childbearing potential who are not currently using reliable contraception.

Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

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

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years; OR
- Patient must have been receiving treatment with this drug prior to 1 December 2013, **AND**
- Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

Authority required

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

teriflunomide 14 mg tablet, 28

2898M

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	5	..	1836.73	38.80	Aubagio [GZ]

■ VARENICLINE

Note A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.

Note A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.

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

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

Authority required (STREAMLINED)**6885**

Nicotine dependence

Treatment Phase: Completion of a short-term (24 weeks) course of treatment

Clinical criteria:

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug during this current course of treatment, **AND**
- Patient must have ceased smoking in the process of completing an initial 12-weeks or ceased smoking following an initial 12-weeks of PBS-subsidised treatment with this drug in the current course of treatment.

Treatment criteria:

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.

varenicline 1 mg tablet, 56

5469W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	109.02	38.80	Champix [PF]

■ VARENICLINE

Note A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.

Note A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.

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

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

Authority required (STREAMLINED)

6864

Nicotine dependence

Treatment Phase: Continuation of a short-term (12 weeks or 24 weeks) course of treatment

Clinical criteria:

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug during this current course of treatment.

Treatment criteria:

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.

varenicline 1 mg tablet, 56

9129L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*208.08	38.80	Champix [PF]

■ VARENICLINE

Note A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.

Note The period between commencing varenicline and bupropion or a new course of varenicline must be at least 6 months.

Note A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.

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

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

Authority required (STREAMLINED)

6871

Nicotine dependence

Treatment Phase: Commencement of a short-term (12 weeks or 24 weeks) course of treatment

Clinical criteria:

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have indicated they are ready to cease smoking, **AND**
- Patient must not receive more than 24 weeks of PBS-subsidised treatment with this drug per 12-month period.

Treatment criteria:

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

Clinical review is recommended within 2 to 3 weeks of the initial prescription being requested.

varenicline 500 microgram tablet [11 tablets] (&) varenicline 1 mg tablet [42 tablets], 53

9128K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	..	..	94.07	38.80	Champix [PF]

Highly Specialised Drugs Program (Private Hospital)

■ ALEMTUZUMAB

Note Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.

Note Special Pricing Arrangements apply.

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

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

Authority required

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must not receive more than one PBS-subsidised treatment per year, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

Treatment criteria:

- Must be treated by a neurologist.

alemtuzumab 12 mg/1.2 mL injection, 1.2 mL vial

10246G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	3	..	..	*34229.01	Lemtrada [GZ]

■ ALEMTUZUMAB

Note Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.

Note Special Pricing Arrangements apply.

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

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

Authority required

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, **AND**
- Patient must be ambulatory (without assistance or support).

Treatment criteria:

- Must be treated by a neurologist.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

alemtuzumab 12 mg/1.2 mL injection, 1.2 mL vial

10243D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	5	..	..	*57017.02	Lemtrada [GZ]

■ IVACAFTOR

Note Special Pricing Arrangements apply.

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

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

Cystic fibrosis

Treatment Phase: Initial treatment - New patients

Clinical criteria:

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR
- Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, **AND**
- Patient must have a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged 2 years or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Cystic Fibrosis Ivacaftor Authority Application Supporting Information Form; and
- (3) a signed patient acknowledgement; or an acknowledgement signed by a parent or authorised guardian, if applicable; and
- (4) a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene; and
- (5) the result of a FEV1 measurement performed within a month prior to the date of application, if aged from 6 years or older. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and
- (6) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and
- (7) a copy of a sweat chloride result; and
- (8) height and weight measurements at the time of application; and
- (9) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 12 months.

Authority required

Cystic fibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged 2 years or older.
- Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry. Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug. Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation. Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks. Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks. Ivacaftor is not PBS-subsidised for this condition as a sole therapy. Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:
- Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort
- Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin
- Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.
- The authority application must be in writing and must include:
- (1) a completed authority prescription form; and
 - (2) a completed Cystic Fibrosis Ivacaftor Authority Continuing Application Supporting Information Form; and
 - (3) the result of a FEV1 measurement performed within one month prior to the date of application, if aged 6 years or older. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and
 - (4) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and
 - (5) height and weight measurements at the time of application; and
 - (6) a measurement of number of days of CF-related hospitalisation (including hospital in the home) in the previous 6 months.

ivacaftor 150 mg tablet, 56

10175M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	22547.02	Kalydeco [VR]

■ IVACAFTOR

Note Special Pricing Arrangements apply.

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

Authority required

Cystic fibrosis

Treatment Phase: Initial treatment - New patients

Clinical criteria:

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR
- Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, **AND**
- Patient must have a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged 2 years or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Cystic Fibrosis Ivacaftor Authority Application Supporting Information Form; and
- (3) a signed patient acknowledgement; or an acknowledgement signed by a parent or authorised guardian, if applicable; and
- (4) a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene; and
- (5) the result of a FEV1 measurement performed within a month prior to the date of application, if aged from 6 years or older. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and
- (6) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and
- (7) a copy of a sweat chloride result; and
- (8) height and weight measurements at the time of application; and
- (9) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 12 months.

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

Cystic fibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged 2 years or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Cystic Fibrosis Ivacaftor Authority Continuing Application Supporting Information Form; and
- (3) the result of a FEV1 measurement performed within one month prior to the date of application, if aged 6 years or older. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and
- (4) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and
- (5) height and weight measurements at the time of application; and
- (6) a measurement of number of days of CF-related hospitalisation (including hospital in the home) in the previous 6 months.

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

Cystic fibrosis

Treatment Phase: Initial treatment - Grandfather patients

Clinical criteria:

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR
- Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, **AND**
- Patient must have received treatment with ivacaftor for this condition prior to 1 May 2017, **AND**
- Patient must have received treatment with ivacaftor within the last 6 months at the time of application, **AND**
- Patient must have a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be 2 to 5 years of age.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Dosage of ivacaftor must not exceed the dose of one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Cystic Fibrosis Ivacaftor Application Supporting Information Form; and
- (3) an acknowledgement signed by a parent, or authorised guardian if applicable; and
- (4) a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene performed prior to commencing treatment with ivacaftor; and
- (5) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and
- (6) a copy of sweat chloride result performed prior to commencing treatment with ivacaftor for this condition; and
- (7) height and weight measurements at the time of application; and
- (8) height and weight measurements performed immediately prior to commencement of ivacaftor; and
- (9) a baseline measurement of number of days of CF-related hospitalisation (including hospital-in-the home) in the 12 months prior to commencement of ivacaftor; and
- (10) a measurement of the number of days of CF-related hospitalisation (including hospital-in the home) in the 6 months prior to the date of application; and
- (11) dates of prior ivacaftor therapy.

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

ivacaftor 50 mg granules, 4 x 14 sachets

11097C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	22547.02	Kalydeco [VR]

ivacaftor 75 mg granules, 4 x 14 sachets

11109Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	22547.02	Kalydeco [VR]

■ LEVODOPA + CARBIDOPA ANHYDROUS

Note Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

Authority required

Advanced Parkinson disease

Clinical criteria:

- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, **AND**
- The treatment must be commenced in a hospital-based movement disorder clinic.

levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL

9744W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*11583.02	Duodopa [VE]

■ NATALIZUMAB

Caution Progressive multifocal leukoencephalopathy has been reported with this drug.

Authority required

Clinically definite relapsing-remitting multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support), **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years, **AND**
- The condition must be confirmed by magnetic resonance imaging of the brain and/or spinal cord; OR
- Patient must be deemed unsuitable for magnetic resonance imaging due to the risk of physical (not psychological) injury to the patient.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a neurologist.

The date of the magnetic resonance imaging scan must be included in the patient's medical notes, unless written certification is provided, in the patient's medical notes, by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient.

Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.

Authority required

Clinically definite relapsing-remitting multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate, this therapy.

Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.

natalizumab 300 mg/15 mL injection, 15 mL vial

9624M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1536.66	Tysabri [BD]

Highly Specialised Drugs Program (Public Hospital)

■ ALEMTUZUMAB

Note Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.

Note Special Pricing Arrangements apply.

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

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

Authority required (STREAMLINED)

6847

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must not receive more than one PBS-subsidised treatment per year, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

Treatment criteria:

- Must be treated by a neurologist.

alemtuzumab 12 mg/1.2 mL injection, 1.2 mL vial

10232M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	3	..	..	*34182.00	Lemtrada [GZ]

■ ALEMTUZUMAB

Note Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.

Note Special Pricing Arrangements apply.

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

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

Authority required (STREAMLINED)

6884

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, **AND**
- Patient must be ambulatory (without assistance or support).

Treatment criteria:

- Must be treated by a neurologist.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

alemtuzumab 12 mg/1.2 mL injection, 1.2 mL vial

10228H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	5	..	..	*56970.00	Lemtrada [GZ]

■ IVACAFTOR

Note Special Pricing Arrangements apply.

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

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

Cystic fibrosis

Treatment Phase: Initial treatment - New patients

Clinical criteria:

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; **OR**
- Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, **AND**
- Patient must have a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged 2 years or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Cystic Fibrosis Ivacaftor Authority Application Supporting Information Form; and
- (3) a signed patient acknowledgement; or an acknowledgement signed by a parent or authorised guardian, if applicable; and
- (4) a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene; and
- (5) the result of a FEV1 measurement performed within a month prior to the date of application, if aged from 6 years or older. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and
- (6) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and
- (7) a copy of a sweat chloride result; and
- (8) height and weight measurements at the time of application; and
- (9) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 12 months.

Authority required

Cystic fibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged 2 years or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
 - (2) a completed Cystic Fibrosis Ivacaftor Authority Continuing Application Supporting Information Form; and
 - (3) the result of a FEV1 measurement performed within one month prior to the date of application, if aged 6 years or older.
- Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and
- (4) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and
 - (5) height and weight measurements at the time of application; and
 - (6) a measurement of number of days of CF-related hospitalisation (including hospital in the home) in the previous 6 months.

ivacaftor 150 mg tablet, 56

10170G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	22500.00	Kalydeco [VR]

■ IVACAFTOR

Note Special Pricing Arrangements apply.

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

Authority required

Cystic fibrosis

Treatment Phase: Initial treatment - New patients

Clinical criteria:

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; **OR**
- Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, **AND**
- Patient must have a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged 2 years or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
 - (2) a completed Cystic Fibrosis Ivacaftor Authority Application Supporting Information Form; and
 - (3) a signed patient acknowledgement; or an acknowledgement signed by a parent or authorised guardian, if applicable; and
 - (4) a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene; and
 - (5) the result of a FEV1 measurement performed within a month prior to the date of application, if aged from 6 years or older.
- Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and
- (6) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and
 - (7) a copy of a sweat chloride result; and
 - (8) height and weight measurements at the time of application; and
 - (9) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 12 months.

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

Cystic fibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged 2 years or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
 - (2) a completed Cystic Fibrosis Ivacaftor Authority Continuing Application Supporting Information Form; and
 - (3) the result of a FEV1 measurement performed within one month prior to the date of application, if aged 6 years or older.
- Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and
- (4) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and

- (5) height and weight measurements at the time of application; and
- (6) a measurement of number of days of CF-related hospitalisation (including hospital in the home) in the previous 6 months.

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

Cystic fibrosis

Treatment Phase: Initial treatment - Grandfather patients

Clinical criteria:

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR
- Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, **AND**
- Patient must have received treatment with ivacaftor for this condition prior to 1 May 2017, **AND**
- Patient must have received treatment with ivacaftor within the last 6 months at the time of application, **AND**
- Patient must have a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be 2 to 5 years of age.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Dosage of ivacaftor must not exceed the dose of one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

The authority application must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Cystic Fibrosis Ivacaftor Application Supporting Information Form; and
- (3) an acknowledgement signed by a parent, or authorised guardian if applicable; and
- (4) a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene performed prior to commencing treatment with ivacaftor; and
- (5) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and
- (6) a copy of sweat chloride result performed prior to commencing treatment with ivacaftor for this condition; and
- (7) height and weight measurements at the time of application; and
- (8) height and weight measurements performed immediately prior to commencement of ivacaftor; and
- (9) a baseline measurement of number of days of CF-related hospitalisation (including hospital-in-the home) in the 12 months prior to commencement of ivacaftor; and
- (10) a measurement of the number of days of CF-related hospitalisation (including hospital-in the home) in the 6 months prior to the date of application; and
- (11) dates of prior ivacaftor therapy.

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

ivacaftor 50 mg granules, 4 x 14 sachets

11105L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	22500.00	Kalydeco [VR]

ivacaftor 75 mg granules, 4 x 14 sachets

11098D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	22500.00	Kalydeco [VR]

▪ LEVODOPA + CARBIDOPA ANHYDROUS

Note Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

Authority required (STREAMLINED)

6863

Advanced Parkinson disease

Clinical criteria:

- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, **AND**
- The treatment must be commenced in a hospital-based movement disorder clinic.

levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL

9743T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*11536.00	Duodopa [VE]

▪ NATALIZUMAB

Caution Progressive multifocal leukoencephalopathy has been reported with this drug.

Authority required (STREAMLINED)

6875

Clinically definite relapsing-remitting multiple sclerosis

Clinical criteria:

- The treatment must be a sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support), **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years, **AND**
- The condition must be confirmed by magnetic resonance imaging of the brain and/or spinal cord; OR
- Patient must be deemed unsuitable for magnetic resonance imaging due to the risk of physical (not psychological) injury to the patient.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a neurologist.

The date of the magnetic resonance imaging scan must be included in the patient's medical notes, unless written certification is provided, in the patient's medical notes, by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient.

Treatment with this drug must cease if there is continuing progression of disability whilst the patient is being treated with this drug.

For continued treatment the patient must demonstrate compliance with, and an ability to tolerate, this drug.

Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.

natalizumab 300 mg/15 mL injection, 15 mL vial

9505G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1489.64	Tysabri [BD]

Highly Specialised Drugs Program (Community Access)

▪ EMTRICITABINE + RILPIVIRINE + TENOFOVIR ALAFENAMIDE

Authority required (STREAMLINED)

4522

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive.

Authority required (STREAMLINED)

4470

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection.

emtricitabine 200 mg + rilpivirine 25 mg + tenofovir alafenamide 25 mg tablet, 30 tablets

11104K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*2016.72	38.80	Odefsey [GI]

▪ EMTRICITABINE + TENOFOVIR ALAFENAMIDE

Authority required (STREAMLINED)

4512

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)

4454

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.

emtricitabine 200 mg + tenofovir alafenamide 10 mg tablet, 30

11099E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1500.72	38.80	Descovy [GI]

emtricitabine 200 mg + tenofovir alafenamide 25 mg tablet, 30

11113X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1500.72	38.80	Descovy [GI]

▪ TENOFOVIR ALAFENAMIDE + EMTRICITABINE + ELVITEGRAVIR + COBICISTAT

Authority required (STREAMLINED)

4522

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive.

Authority required (STREAMLINED)

4470

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection.

tenofovir alafenamide 10 mg + emtricitabine 200 mg + elvitegravir 150 mg + cobicistat 150 mg tablet, 30

11114Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*2016.72	38.80	Genvoya [GI]