



Australian Government

Department of Health



Schedule of Pharmaceutical Benefits

Summary of Changes

Effective 1 August 2018



Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 August 2018 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	\$7.29
	Dangerous drug fee	\$3.07
	Extemporaneously-prepared	\$9.33
	Allowable additional patient charge*	\$4.45
Additional Fees (for safety net prices):	Ready-prepared	\$1.23
	Extemporaneously-prepared	\$1.59
Patient Co-payments:	General	\$39.50
	Concessional	\$6.40
Safety Net Thresholds:	General	\$1521.80
	Concessional	\$384.00
Safety Net Card Issue Fee:		\$9.91

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

Summary of Changes

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 August 2018. The Schedule is updated on the first day of each month and is available on the internet at www.pbs.gov.au.

Prescriber Bag

Deletions

Deletion – Item

10244E **DIPHTHERIA TOXOID + TETANUS TOXOID**, diphtheria toxoid 2 Lf/0.5 mL + tetanus toxoid 2 Lf/0.5 mL injection, 10 x 0.5 mL vials (*MassBiologics tetanus and diphtheria toxoids adsorbed*)

Alterations

Alteration – Item Description

From

3472R **DEXAMETHASONE SODIUM PHOSPHATE**, DEXAMETHASONE SODIUM PHOSPHATE Injection equivalent to 4 mg dexamethasone phosphate in 1 mL, 5 (*Dexamethasone Mylan, Hospira Pty Limited*)

To

3472R **DEXAMETHASONE PHOSPHATE**, DEXAMETHASONE SODIUM PHOSPHATE Injection equivalent to 4 mg dexamethasone phosphate in 1 mL, 5 (*Dexamethasone Mylan, Hospira Pty Limited*)

Alteration – Manufacturer Code

		From	To
3466K	<i>Frusemide-Clarix</i> – FUROSEMIDE (FRUSEMIDE) , furosemide (frusemide) 20 mg/2 mL injection, 5 x 2 mL ampoules	AE	BX

General Pharmaceutical Benefits

Additions

Addition – Item

11408K **EZETIMIBE**, ezetimibe 10 mg tablet, 30 (*APO-Ezetimibe, Blooms The Chemist Ezetimibe, EZEMICHOL, Ezetrol, Pharmacor Ezetimibe 10, Zient 10mg*)

11344C **GLECAPREVIR + PIBRENTASVIR**, glecaprevir 100 mg + pibrentasvir 40 mg film-coated tablet, 84 (*Maviret*)

11353M **GLECAPREVIR + PIBRENTASVIR**, glecaprevir 100 mg + pibrentasvir 40 mg film-coated tablet, 84 (*Maviret*)

11354N **GLECAPREVIR + PIBRENTASVIR**, glecaprevir 100 mg + pibrentasvir 40 mg film-coated tablet, 84 (*Maviret*)

11419B **IBRUTINIB**, ibrutinib 140 mg capsule, 120 (*Imbruvica*)

11417X **INSULIN DEGLUDEC + INSULIN ASPART**, insulin degludec 70 units/mL + insulin aspart 30 units/mL injection, 5 x 3 mL injection devices (*Ryzodeg Flextouch*)

11426J **INSULIN DEGLUDEC + INSULIN ASPART**, insulin degludec 70 units/mL + insulin aspart 30 units/mL injection, 5 x 3 mL cartridges (*Ryzodeg Penfill*)

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

11436X **PERAMPANEL**, perampanel 2 mg tablet, 7 (*Fycompa*)

11418Y **PERAMPANEL**, perampanel 4 mg tablet, 28 (*Fycompa*)

11407J **PERAMPANEL**, perampanel 6 mg tablet, 28 (*Fycompa*)

11429M **PERAMPANEL**, perampanel 8 mg tablet, 28 (*Fycompa*)

11428L	PERAMPANEL , perampanel 10 mg tablet, 28 (<i>Fycompa</i>)
11409L	PERAMPANEL , perampanel 12 mg tablet, 28 (<i>Fycompa</i>)
11413Q	PERICIAZINE , periciazine 2.5 mg tablet, 84 (<i>Neulactil</i>)
11427K	PERICIAZINE , periciazine 10 mg tablet, 84 (<i>Neulactil</i>)
11406H	PIRFENIDONE , pirfenidone 267 mg tablet, 90 (<i>Esbriet</i>)
11410M	PIRFENIDONE , pirfenidone 801 mg tablet, 90 (<i>Esbriet</i>)

Addition – Brand

1007B	<i>APO-Aciclovir, TX</i> – ACICLOVIR , aciclovir 200 mg tablet, 90
1555W	<i>APO-Aciclovir, TX</i> – ACICLOVIR , aciclovir 200 mg tablet, 50
1052J	<i>APO-Aciclovir, TX</i> – ACICLOVIR , aciclovir 800 mg tablet, 35
9317J	<i>Clopidogrel Sandoz, SZ</i> – CLOPIDOGREL , clopidogrel 75 mg tablet, 28
8757X	<i>APO-Ezetimibe, TX</i> – EZETIMIBE , ezetimibe 10 mg tablet, 30
8757X	<i>Blooms The Chemist Ezetimibe, IB</i> – EZETIMIBE , ezetimibe 10 mg tablet, 30
8757X	<i>EZEMICHOL, RW</i> – EZETIMIBE , ezetimibe 10 mg tablet, 30
8757X	<i>Ezetimibe GH, GQ</i> – EZETIMIBE , ezetimibe 10 mg tablet, 30
8757X	<i>Ezetimibe Sandoz, SZ</i> – EZETIMIBE , ezetimibe 10 mg tablet, 30
9483D	<i>APO-Ezetimibe/Simvastatin 10/10, TX</i> – EZETIMIBE + SIMVASTATIN , ezetimibe 10 mg + simvastatin 10 mg tablet, 30
9483D	<i>EZETIMIBE/SIMVASTATIN SANDOZ, SZ</i> – EZETIMIBE + SIMVASTATIN , ezetimibe 10 mg + simvastatin 10 mg tablet, 30
9484E	<i>APO-Ezetimibe/Simvastatin 10/20, TX</i> – EZETIMIBE + SIMVASTATIN , ezetimibe 10 mg + simvastatin 20 mg tablet, 30
9484E	<i>EZETIMIBE/SIMVASTATIN SANDOZ, SZ</i> – EZETIMIBE + SIMVASTATIN , ezetimibe 10 mg + simvastatin 20 mg tablet, 30
8881K	<i>APO-Ezetimibe/Simvastatin 10/40, TX</i> – EZETIMIBE + SIMVASTATIN , ezetimibe 10 mg + simvastatin 40 mg tablet, 30
8881K	<i>EZETIMIBE/SIMVASTATIN SANDOZ, SZ</i> – EZETIMIBE + SIMVASTATIN , ezetimibe 10 mg + simvastatin 40 mg tablet, 30
8882L	<i>APO-Ezetimibe/Simvastatin 10/80, TX</i> – EZETIMIBE + SIMVASTATIN , ezetimibe 10 mg + simvastatin 80 mg tablet, 30
8882L	<i>EZETIMIBE/SIMVASTATIN SANDOZ, SZ</i> – EZETIMIBE + SIMVASTATIN , ezetimibe 10 mg + simvastatin 80 mg tablet, 30
1475P	<i>Fluconazole APOTEX, GX</i> – FLUCONAZOLE , fluconazole 200 mg capsule, 28
1834M	<i>Gabapentin generichealth, HQ</i> – GABAPENTIN , gabapentin 300 mg capsule, 100
1835N	<i>Gabapentin generichealth, HQ</i> – GABAPENTIN , gabapentin 400 mg capsule, 100
2851C	<i>Sandoz Lamotrigine, HX</i> – LAMOTRIGINE , lamotrigine 200 mg tablet, 56
8534E	<i>Zircol 10, AL</i> – LERCANIDIPINE , lercanidipine hydrochloride 10 mg tablet, 28
8679T	<i>Zircol 20, AL</i> – LERCANIDIPINE , lercanidipine hydrochloride 20 mg tablet, 28
1900B	<i>APO-Moclobemide, TX</i> – MOCLOBEMIDE , moclobemide 150 mg tablet, 60
8003F	<i>APO-Moclobemide, TX</i> – MOCLOBEMIDE , moclobemide 300 mg tablet, 60
9019Q	<i>APO-Moxonidine, TX</i> – MOXONIDINE , moxonidine 200 microgram tablet, 30
9020R	<i>APO-Moxonidine, TX</i> – MOXONIDINE , moxonidine 400 microgram tablet, 30
9316H	<i>APO-Nebivolol, TX</i> – NEBIVOLOL , nebivolol 1.25 mg tablet, 28
9311C	<i>APO-Nebivolol, TX</i> – NEBIVOLOL , nebivolol 5 mg tablet, 28
9312D	<i>APO-Nebivolol, TX</i> – NEBIVOLOL , nebivolol 10 mg tablet, 28
1897W	<i>APO-Piroxicam, TX</i> – PIROXICAM , piroxicam 10 mg capsule, 50
5203W	<i>APO-Piroxicam, TX</i> – PIROXICAM , piroxicam 10 mg capsule, 50

1898X APO-Piroxicam, TX – **PIROXICAM**, piroxicam 20 mg capsule, 25
 5204X APO-Piroxicam, TX – **PIROXICAM**, piroxicam 20 mg capsule, 25

Addition – Equivalence Indicator

9316H Nebilet, FK – **NEBIVOLOL**, nebivolol 1.25 mg tablet, 28
 9311C Nebilet, FK – **NEBIVOLOL**, nebivolol 5 mg tablet, 28
 9312D Nebilet, FK – **NEBIVOLOL**, nebivolol 10 mg tablet, 28

Addition – Note

10124W **ACLIDINIUM**, acclidinium 322 microgram/actuation inhalation: powder for, 60 actuations (*Bretaris Genuair*)
 10024N **BUDESONIDE + FORMOTEROL (EFORMOTEROL)**, budesonide 50 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 3 microgram/actuation pressurised inhalation, 120 actuations (*Symbicort Rapihaler 50/3*)
 10015D **BUDESONIDE + FORMOTEROL (EFORMOTEROL)**, budesonide 100 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 3 microgram/actuation pressurised inhalation, 120 actuations (*Symbicort Rapihaler 100/3*)
 8796Y **BUDESONIDE + FORMOTEROL (EFORMOTEROL)**, budesonide 100 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations (*Symbicort Turbuhaler 100/6*)
 11273H **BUDESONIDE + FORMOTEROL (EFORMOTEROL)**, budesonide 200 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations (*DuoResp Spiromax*)
 8625Y **BUDESONIDE + FORMOTEROL (EFORMOTEROL)**, budesonide 200 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations (*Symbicort Turbuhaler 200/6*)
 2827T **FLUTICASONE + FORMOTEROL (EFORMOTEROL)**, fluticasone propionate 50 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 5 microgram/actuation pressurised inhalation, 120 actuations (*flutiform 50/5*)
 10007Q **FLUTICASONE + FORMOTEROL (EFORMOTEROL)**, fluticasone propionate 125 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 5 microgram/actuation pressurised inhalation, 120 actuations (*flutiform 125/5*)
 10008R **FLUTICASONE + FORMOTEROL (EFORMOTEROL)**, fluticasone propionate 250 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 10 microgram/actuation pressurised inhalation, 120 actuations (*flutiform 250/10*)
 8517G **FLUTICASONE + SALMETEROL**, fluticasone propionate 50 microgram/actuation + salmeterol 25 microgram/actuation pressurised inhalation, 120 actuations (*Seretide MDI 50/25*)
 8518H **FLUTICASONE + SALMETEROL**, fluticasone propionate 125 microgram/actuation + salmeterol 25 microgram/actuation pressurised inhalation, 120 actuations (*Fluticasone + Salmeterol Cipla 125/25, SalplusF Inhaler 125/25, Seretide MDI 125/25*)
 8430Q **FLUTICASONE + SALMETEROL**, fluticasone propionate 100 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations (*Seretide Accuhaler 100/50*)
 8431R **FLUTICASONE + SALMETEROL**, fluticasone propionate 250 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations (*Seretide Accuhaler 250/50*)
 11129R **FLUTICASONE FUROATE + VILANTEROL**, fluticasone furoate 200 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations (*Breo Ellipta 200/25*)
 10865W **FOLLITROPIN ALFA**, follitropin alfa 75 units (5.5 microgram)/0.125 mL injection, 5 x 0.125 mL injection devices (*Bemfola*)
 10877L **FOLLITROPIN ALFA**, follitropin alfa 150 units (11 microgram)/0.25 mL injection, 5 x 0.25 mL injection devices (*Bemfola*)
 10876K **FOLLITROPIN ALFA**, follitropin alfa 225 units (16.5 microgram)/0.375 mL injection, 5 x 0.375 mL injection devices (*Bemfola*)
 8713N **FOLLITROPIN ALFA**, follitropin alfa 300 units (21.84 microgram)/0.5 mL injection, 0.5 mL cartridge (*Gonal-f Pen*)
 8714P **FOLLITROPIN ALFA**, follitropin alfa 450 units (32.76 microgram)/0.75 mL injection, 0.75 mL cartridge (*Gonal-f Pen*)
 8715Q **FOLLITROPIN ALFA**, follitropin alfa 900 units (65.52 microgram)/1.5 mL injection, 1.5 mL cartridge (*Gonal-f Pen*)
 10059K **GLYCOPYRRONIUM**, glycopyrronium 50 microgram powder for inhalation, 30 capsules (*seebri breezhaler*)
 5134F **INDACATEROL**, indacaterol 150 microgram powder for inhalation, 30 capsules (*Onbrez*)

5137J	INDACATEROL , indacaterol 300 microgram powder for inhalation, 30 capsules (<i>Onbrez</i>)
1542E	IPRATROPIUM , ipratropium bromide 250 microgram/mL inhalation solution, 30 x 1 mL ampoules (<i>APO-Ipratropium, Aeron 250, Atrovent, Ipratrin</i>)
8238N	IPRATROPIUM , ipratropium bromide 500 microgram/mL inhalation solution, 30 x 1 mL ampoules (<i>APO-Ipratropium, Aeron 500, Atrovent Adult, Ipratrin Adult</i>)
11130T	SALBUTAMOL , salbutamol 2.5 mg/2.5 mL inhalation solution, 20 x 2.5 mL ampoules (<i>Ventolin Nebules</i>)
2000G	SALBUTAMOL , salbutamol 2.5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules (<i>APO-Salbutamol, Asmol 2.5 uni-dose, Salbutamol AN, Salbutamol Actavis, Salbutamol Sandoz</i>)
11095Y	SALBUTAMOL , salbutamol 5 mg/2.5 mL inhalation solution, 20 x 2.5 mL ampoules (<i>Ventolin Nebules</i>)
2001H	SALBUTAMOL , salbutamol 5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules (<i>APO-Salbutamol, Asmol 5 uni-dose, Salbutamol AN, Salbutamol Actavis, Salbutamol Sandoz</i>)
8626B	TIOTROPIUM , tiotropium 18 microgram powder for inhalation, 30 capsules (<i>Spiriva</i>)
10509D	TIOTROPIUM , tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations (<i>Spiriva Respimat</i>)
10187E	UMECLIDINIUM , umeclidinium 62.5 microgram/actuation inhalation: powder for, 30 actuations (<i>Incruse Ellipta</i>)

Deletions

Deletion – Item

10261C	DIPHTHERIA TOXOID + TETANUS TOXOID , diphtheria toxoid 2 Lf/0.5 mL + tetanus toxoid 2 Lf/0.5 mL injection, 10 x 0.5 mL vials (<i>MassBiologics tetanus and diphtheria toxoids adsorbed</i>)
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Deletion – Brand

9049G	<i>APO-Amlodipine/Atorvastatin 5/10, TX</i> – AMLODIPINE + ATORVASTATIN , amlodipine 5 mg + atorvastatin 10 mg tablet, 30
9050H	<i>APO-Amlodipine/Atorvastatin 5/20, TX</i> – AMLODIPINE + ATORVASTATIN , amlodipine 5 mg + atorvastatin 20 mg tablet, 30
9051J	<i>APO-Amlodipine/Atorvastatin 5/40, TX</i> – AMLODIPINE + ATORVASTATIN , amlodipine 5 mg + atorvastatin 40 mg tablet, 30
9052K	<i>APO-Amlodipine/Atorvastatin 5/80, TX</i> – AMLODIPINE + ATORVASTATIN , amlodipine 5 mg + atorvastatin 80 mg tablet, 30
9053L	<i>APO-Amlodipine/Atorvastatin 10/10, TX</i> – AMLODIPINE + ATORVASTATIN , amlodipine 10 mg + atorvastatin 10 mg tablet, 30
9054M	<i>APO-Amlodipine/Atorvastatin 10/20, TX</i> – AMLODIPINE + ATORVASTATIN , amlodipine 10 mg + atorvastatin 20 mg tablet, 30
9055N	<i>APO-Amlodipine/Atorvastatin 10/40, TX</i> – AMLODIPINE + ATORVASTATIN , amlodipine 10 mg + atorvastatin 40 mg tablet, 30
9056P	<i>APO-Amlodipine/Atorvastatin 10/80, TX</i> – AMLODIPINE + ATORVASTATIN , amlodipine 10 mg + atorvastatin 80 mg tablet, 30
1892N	<i>APO-Amoxicillin and Clavulanic Acid 125/31.25, TX</i> – AMOXICILLIN + CLAVULANIC ACID , amoxicillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL powder for oral liquid, 75 mL
5009P	<i>APO-Amoxicillin and Clavulanic Acid 125/31.25, TX</i> – AMOXICILLIN + CLAVULANIC ACID , amoxicillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL powder for oral liquid, 75 mL
5011R	<i>APO-Amoxicillin and Clavulanic Acid 400/57, TX</i> – AMOXICILLIN + CLAVULANIC ACID , amoxicillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL powder for oral liquid, 60 mL
8319W	<i>APO-Amoxicillin and Clavulanic Acid 400/57, TX</i> – AMOXICILLIN + CLAVULANIC ACID , amoxicillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL powder for oral liquid, 60 mL
10778G	<i>Rancef, RA</i> – CEFALEXIN , cefalexin 500 mg capsule, 20
3119E	<i>Rancef, RA</i> – CEFALEXIN , cefalexin 500 mg capsule, 20
3318P	<i>Rancef, RA</i> – CEFALEXIN , cefalexin 500 mg capsule, 20
2479L	<i>Donepezil RBX, RA</i> – DONEPEZIL , donepezil hydrochloride 10 mg tablet, 28
8496E	<i>Donepezil RBX, RA</i> – DONEPEZIL , donepezil hydrochloride 10 mg tablet, 28
1834M	<i>Gabapentin GH, GQ</i> – GABAPENTIN , gabapentin 300 mg capsule, 100
1835N	<i>Gabapentin GH, GQ</i> – GABAPENTIN , gabapentin 400 mg capsule, 100

8656N	<i>Levitaccord, RA</i> – LEVETIRACETAM , levetiracetam 1 g tablet, 60
8561N	<i>Meloxicam Ranbaxy, RA</i> – MELOXICAM , meloxicam 7.5 mg tablet, 30
8562P	<i>Meloxicam Ranbaxy, RA</i> – MELOXICAM , meloxicam 15 mg tablet, 30
8607B	<i>Metformin Ranbaxy 1000, RA</i> – METFORMIN , metformin hydrochloride 1 g tablet, 90
8197K	<i>Pravastatin generichealth, GQ</i> – PRAVASTATIN , pravastatin sodium 40 mg tablet, 30
9239G	<i>Pravastatin generichealth, GQ</i> – PRAVASTATIN , pravastatin sodium 40 mg tablet, 30
8507R	<i>Rabeprazole generichealth, GQ</i> – RABEPRAZOLE , rabeprazole sodium 10 mg enteric tablet, 28
9121C	<i>Ramipril generichealth, GQ</i> – RAMIPRIL , ramipril 2.5 mg capsule, 30
9122D	<i>Ramipril generichealth, GQ</i> – RAMIPRIL , ramipril 5 mg capsule, 30
8470T	<i>Ramipril generichealth, GQ</i> – RAMIPRIL , ramipril 10 mg capsule, 30
11049M	<i>Repalyte New Formulation, SW</i> – SODIUM CHLORIDE + POTASSIUM CHLORIDE + GLUCOSE MONOHYDRATE + CITRIC ACID , sodium chloride 470 mg + potassium chloride 300 mg + glucose monohydrate 3.56 g + sodium acid citrate 530 mg powder for oral liquid, 10 x 4.9 g sachets
3196F	<i>Repalyte New Formulation, SW</i> – SODIUM CHLORIDE + POTASSIUM CHLORIDE + GLUCOSE MONOHYDRATE + CITRIC ACID , sodium chloride 470 mg + potassium chloride 300 mg + glucose monohydrate 3.56 g + sodium acid citrate 530 mg powder for oral liquid, 10 x 4.9 g sachets

Deletion – Equivalence Indicator

1892N	<i>Curam, SZ</i> – AMOXICILLIN + CLAVULANIC ACID , amoxicillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL powder for oral liquid, 75 mL
5009P	<i>Curam, SZ</i> – AMOXICILLIN + CLAVULANIC ACID , amoxicillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL powder for oral liquid, 75 mL
11049M	<i>restore O.R.S., EA</i> – SODIUM CHLORIDE + POTASSIUM CHLORIDE + GLUCOSE MONOHYDRATE + CITRIC ACID , sodium chloride 470 mg + potassium chloride 300 mg + glucose monohydrate 3.56 g + sodium acid citrate 530 mg powder for oral liquid, 10 x 4.9 g sachets

Deletion – Note

3196F	SODIUM CHLORIDE + POTASSIUM CHLORIDE + GLUCOSE MONOHYDRATE + CITRIC ACID , sodium chloride 470 mg + potassium chloride 300 mg + glucose monohydrate 3.56 g + sodium acid citrate 530 mg powder for oral liquid, 10 x 4.9 g sachets (<i>O.R.S., restore O.R.S.</i>)
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Deletion – Caution

11037X	PEGINTERFERON ALFA-2A , peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes (<i>Pegasys</i>)
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Deletion – Restriction

8757X	EZETIMIBE , ezetimibe 10 mg tablet, 30 (<i>APO-Ezetimibe, Blooms The Chemist Ezetimibe, EZEMICHOL, Ezetimibe GH, Ezetimibe Sandoz, Ezetrol, Pharmacor Ezetimibe 10, Zient 10mg</i>)
11100F	NINTEDANIB , nintedanib 100 mg capsule, 60 (<i>Ofev</i>)
11106M	NINTEDANIB , nintedanib 150 mg capsule, 60 (<i>Ofev</i>)
11136D	PIRFENIDONE , pirfenidone 267 mg capsule, 270 (<i>Esbriet</i>)

Alterations

Alteration – Item Description

From	
1788D	CEFTRIAXONE , CEFTRIAXONE Powder for injection 1 g, 5 (<i>Ceftriaxone Alphapharm</i>)
To	
1788D	CEFTRIAXONE , ceftriaxone 1 g injection, 5 vials (<i>Ceftriaxone Alphapharm</i>)

<i>From</i> 2509C	DEXAMETHASONE SODIUM PHOSPHATE , DEXAMETHASONE SODIUM PHOSPHATE Injection equivalent to 4 mg dexamethasone phosphate in 1 mL, 5 (<i>Dexamethasone Mylan, Hospira Pty Limited</i>)
<i>To</i> 2509C	DEXAMETHASONE PHOSPHATE , DEXAMETHASONE SODIUM PHOSPHATE Injection equivalent to 4 mg dexamethasone phosphate in 1 mL, 5 (<i>Dexamethasone Mylan, Hospira Pty Limited</i>)
<i>From</i> 1291Y	DEXAMETHASONE SODIUM PHOSPHATE , DEXAMETHASONE SODIUM PHOSPHATE Injection equivalent to 8 mg dexamethasone phosphate in 2 mL, 5 (<i>Dexamethasone Mylan, Hospira Pty Limited</i>)
<i>To</i> 1291Y	DEXAMETHASONE PHOSPHATE , DEXAMETHASONE SODIUM PHOSPHATE Injection equivalent to 8 mg dexamethasone phosphate in 2 mL, 5 (<i>Dexamethasone Mylan, Hospira Pty Limited</i>)
<i>From</i> 10295W	ESOMEPRAZOLE , esomeprazole 20 mg capsule, 30 (<i>Esomeprazole ACTAVIS, Noxicid Caps</i>)
<i>To</i> 10295W	ESOMEPRAZOLE , esomeprazole 20 mg enteric capsule, 30 (<i>Esomeprazole ACTAVIS, Noxicid Caps</i>)
<i>From</i> 10343J	ESOMEPRAZOLE , esomeprazole 20 mg capsule, 30 (<i>Esomeprazole ACTAVIS, Noxicid Caps</i>)
<i>To</i> 10343J	ESOMEPRAZOLE , esomeprazole 20 mg enteric capsule, 30 (<i>Esomeprazole ACTAVIS, Noxicid Caps</i>)
<i>From</i> 10330Q	ESOMEPRAZOLE , esomeprazole 40 mg capsule, 30 (<i>Esomeprazole ACTAVIS, Noxicid Caps</i>)
<i>To</i> 10330Q	ESOMEPRAZOLE , esomeprazole 40 mg enteric capsule, 30 (<i>Esomeprazole ACTAVIS, Noxicid Caps</i>)
<i>From</i> 10331R	ESOMEPRAZOLE , esomeprazole 40 mg capsule, 30 (<i>Esomeprazole ACTAVIS, Noxicid Caps</i>)
<i>To</i> 10331R	ESOMEPRAZOLE , esomeprazole 40 mg enteric capsule, 30 (<i>Esomeprazole ACTAVIS, Noxicid Caps</i>)
<i>From</i> 11198J	ETANERCEPT , ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (<i>Enbrel</i>)
<i>To</i> 11198J	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL injection devices (<i>Enbrel</i>)
<i>From</i> 11201M	ETANERCEPT , ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (<i>Enbrel</i>)
<i>To</i> 11201M	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL injection devices (<i>Enbrel</i>)
<i>From</i> 11202N	ETANERCEPT , ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (<i>Brenzys</i>)
<i>To</i> 11202N	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL injection devices (<i>Brenzys</i>)
<i>From</i> 11215G	ETANERCEPT , ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (<i>Brenzys</i>)
<i>To</i> 11215G	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL injection devices (<i>Brenzys</i>)
<i>From</i> 11218K	ETANERCEPT , ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (<i>Brenzys</i>)
<i>To</i> 11218K	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL injection devices (<i>Brenzys</i>)
<i>From</i> 11220M	ETANERCEPT , ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (<i>Enbrel</i>)
<i>To</i> 11220M	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL injection devices (<i>Enbrel</i>)
<i>From</i> 11221N	ETANERCEPT , ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (<i>Brenzys</i>)
<i>To</i> 11221N	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL injection devices (<i>Brenzys</i>)
<i>From</i> 11222P	ETANERCEPT , ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (<i>Enbrel</i>)
<i>To</i> 11222P	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL injection devices (<i>Enbrel</i>)

From
 1964J **ETANERCEPT**, ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (*Enbrel*)
 To
 1964J **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL injection devices (*Enbrel*)

From
 3447K **ETANERCEPT**, ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (*Enbrel*)
 To
 3447K **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL injection devices (*Enbrel*)

From
 3450N **ETANERCEPT**, ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (*Enbrel*)
 To
 3450N **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL injection devices (*Enbrel*)

From
 9455P **ETANERCEPT**, ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (*Brenzys, Enbrel*)
 To
 9455P **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL injection devices (*Brenzys, Enbrel*)

From
 9456Q **ETANERCEPT**, ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (*Brenzys, Enbrel*)
 To
 9456Q **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL injection devices (*Brenzys, Enbrel*)

From
 9457R **ETANERCEPT**, ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (*Brenzys, Enbrel*)
 To
 9457R **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL injection devices (*Brenzys, Enbrel*)

From
 9458T **ETANERCEPT**, ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (*Brenzys, Enbrel*)
 To
 9458T **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL injection devices (*Brenzys, Enbrel*)

From
 9459W **ETANERCEPT**, ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (*Brenzys, Enbrel*)
 To
 9459W **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL injection devices (*Brenzys, Enbrel*)

From
 9460X **ETANERCEPT**, ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (*Brenzys, Enbrel*)
 To
 9460X **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL injection devices (*Brenzys, Enbrel*)

From
 9461Y **ETANERCEPT**, ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (*Brenzys, Enbrel*)
 To
 9461Y **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL injection devices (*Brenzys, Enbrel*)

From
 9462B **ETANERCEPT**, ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (*Brenzys, Enbrel*)
 To
 9462B **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL injection devices (*Brenzys, Enbrel*)

From
 11196G **ETANERCEPT**, ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (*Enbrel*)
 To
 11196G **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL syringes (*Enbrel*)

From
 11208X **ETANERCEPT**, ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (*Enbrel*)
 To
 11208X **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL syringes (*Enbrel*)

From
 11211C **ETANERCEPT**, ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (*Brenzys*)
 To
 11211C **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL syringes (*Brenzys*)

From
 11216H **ETANERCEPT**, ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (*Brenzys*)
 To
 11216H **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL syringes (*Brenzys*)

From 11217J	ETANERCEPT , ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (<i>Brenzys</i>)
To 11217J	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Brenzys</i>)
From 11219L	ETANERCEPT , ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (<i>Enbrel</i>)
To 11219L	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Enbrel</i>)
From 11224R	ETANERCEPT , ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (<i>Enbrel</i>)
To 11224R	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Enbrel</i>)
From 11225T	ETANERCEPT , ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (<i>Brenzys</i>)
To 11225T	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Brenzys</i>)
From 1963H	ETANERCEPT , ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (<i>Enbrel</i>)
To 1963H	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Enbrel</i>)
From 3446J	ETANERCEPT , ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (<i>Enbrel</i>)
To 3446J	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Enbrel</i>)
From 3449M	ETANERCEPT , ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (<i>Enbrel</i>)
To 3449M	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Enbrel</i>)
From 9085E	ETANERCEPT , ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (<i>Brenzys</i> , <i>Enbrel</i>)
To 9085E	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Brenzys</i> , <i>Enbrel</i>)
From 9086F	ETANERCEPT , ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (<i>Brenzys</i> , <i>Enbrel</i>)
To 9086F	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Brenzys</i> , <i>Enbrel</i>)
From 9087G	ETANERCEPT , ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (<i>Brenzys</i> , <i>Enbrel</i>)
To 9087G	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Brenzys</i> , <i>Enbrel</i>)
From 9088H	ETANERCEPT , ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (<i>Brenzys</i> , <i>Enbrel</i>)
To 9088H	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Brenzys</i> , <i>Enbrel</i>)
From 9089J	ETANERCEPT , ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (<i>Brenzys</i> , <i>Enbrel</i>)
To 9089J	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Brenzys</i> , <i>Enbrel</i>)
From 9090K	ETANERCEPT , ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (<i>Brenzys</i> , <i>Enbrel</i>)
To 9090K	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Brenzys</i> , <i>Enbrel</i>)
From 9091L	ETANERCEPT , ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (<i>Brenzys</i> , <i>Enbrel</i>)
To 9091L	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Brenzys</i> , <i>Enbrel</i>)
From 9431J	ETANERCEPT , ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (<i>Brenzys</i> , <i>Enbrel</i>)
To 9431J	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Brenzys</i> , <i>Enbrel</i>)

From 10359F	GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS , glycomacropeptide and essential amino acids with vitamins and minerals containing 10 g protein oral liquid, 30 x 250 mL cartons (<i>PKU Glytactin RTD 10</i>)
To 10359F	GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS , glycomacropeptide and essential amino acids with vitamins and minerals containing 10 g of protein equivalent oral liquid, 30 x 250 mL cartons (<i>PKU Glytactin RTD 10</i>)
From 10528D	GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS , glycomacropeptide and essential amino acids with vitamins and minerals 15 g protein equivalent oral liquid, 30 x 250 mL cartons (<i>Tylactin RTD</i>)
To 10528D	GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS , glycomacropeptide and essential amino acids with vitamins and minerals containing 15 g of protein equivalent oral liquid, 30 x 250 mL cartons (<i>Tylactin RTD</i>)
From 10652P	GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS , glycomacropeptide and essential amino acids with vitamins and minerals oral liquid: powder for, 30 x 49 g sachets (<i>Camino Pro Bettermilk</i>)
To 10652P	GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS , glycomacropeptide and essential amino acids with vitamins and minerals powder for oral liquid, 30 x 49 g sachets (<i>Camino Pro Bettermilk</i>)
From 2886X	HONEY BEE VENOM , bee venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial] (&) inert substance diluent [3 x 1.8 mL vials], 1 pack (<i>Albey Bee Venom</i>)
To 2886X	HONEY BEE VENOM , honey bee venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial] (&) inert substance diluent [3 x 1.8 mL vials], 1 pack (<i>Albey Bee Venom</i>)
From 8855C	MIRTAZAPINE , MIRTAZAPINE Tablet 15 mg (orally disintegrating), 30 (<i>Avanza SolTab, Milivin OD 15, Mirtazapine AN ODT, Mirtazapine Sandoz ODT 15, Remeron SolTab</i>)
To 8855C	MIRTAZAPINE , mirtazapine 15 mg orally disintegrating tablet, 30 (<i>Avanza SolTab, Milivin OD 15, Mirtazapine AN ODT, Mirtazapine Sandoz ODT 15, Remeron SolTab</i>)
From 8856D	MIRTAZAPINE , MIRTAZAPINE Tablet 30 mg (orally disintegrating), 30 (<i>Avanza SolTab, Milivin OD 30, Mirtazapine AN ODT, Mirtazapine Sandoz ODT 30, Remeron SolTab</i>)
To 8856D	MIRTAZAPINE , mirtazapine 30 mg orally disintegrating tablet, 30 (<i>Avanza SolTab, Milivin OD 30, Mirtazapine AN ODT, Mirtazapine Sandoz ODT 30, Remeron SolTab</i>)
From 8857E	MIRTAZAPINE , MIRTAZAPINE Tablet 45 mg (orally disintegrating), 30 (<i>Avanza SolTab, Milivin OD 45, Mirtazapine AN ODT, Mirtazapine Sandoz ODT 45, Remeron SolTab</i>)
To 8857E	MIRTAZAPINE , mirtazapine 45 mg orally disintegrating tablet, 30 (<i>Avanza SolTab, Milivin OD 45, Mirtazapine AN ODT, Mirtazapine Sandoz ODT 45, Remeron SolTab</i>)
From 2147B	OLMESARTAN MEDOXOMIL , olmesartan medoxomil 20 mg tablet, 30 (<i>APO-Olmesartan, OLMERTAN, Olmesartan - MYL, Olmesartan AN, Olmesartan Sandoz, Olmetec, Pharmacor Olmesartan 20</i>)
To 2147B	OLMESARTAN , olmesartan medoxomil 20 mg tablet, 30 (<i>APO-Olmesartan, OLMERTAN, Olmesartan - MYL, Olmesartan AN, Olmesartan Sandoz, Olmetec, Pharmacor Olmesartan 20</i>)
From 2148C	OLMESARTAN MEDOXOMIL , olmesartan medoxomil 40 mg tablet, 30 (<i>APO-Olmesartan, OLMERTAN, Olmesartan - MYL, Olmesartan AN, Olmesartan Sandoz, Olmetec, Pharmacor Olmesartan 40</i>)
To 2148C	OLMESARTAN , olmesartan medoxomil 40 mg tablet, 30 (<i>APO-Olmesartan, OLMERTAN, Olmesartan - MYL, Olmesartan AN, Olmesartan Sandoz, Olmetec, Pharmacor Olmesartan 40</i>)

From 1326T	OMEPRAZOLE , omeprazole 20 mg capsule, 30 (<i>APO-Omeprazole, Maxor, Omeprazole Sandoz, Pemzo, Pharmacor Omeprazole 20, Probitor</i>)
To 1326T	OMEPRAZOLE , omeprazole 20 mg enteric capsule, 30 (<i>APO-Omeprazole, Maxor, Omeprazole Sandoz, Pemzo, Pharmacor Omeprazole 20, Probitor</i>)
From 1327W	OMEPRAZOLE , omeprazole 20 mg capsule, 30 (<i>APO-Omeprazole, Maxor, Omeprazole Sandoz, Pemzo, Pharmacor Omeprazole 20, Probitor</i>)
To 1327W	OMEPRAZOLE , omeprazole 20 mg enteric capsule, 30 (<i>APO-Omeprazole, Maxor, Omeprazole Sandoz, Pemzo, Pharmacor Omeprazole 20, Probitor</i>)
From 11200L	VITAMINS, MINERALS AND TRACE ELEMENTS FORMULA , vitamins, minerals and trace elements formula powder for oral liquid, 30 x 7 g sachets (<i>Phlexy-Vits</i>)
To 11200L	VITAMINS, MINERALS AND TRACE ELEMENTS , vitamins, minerals and trace elements powder for oral liquid, 30 x 7 g sachets (<i>Phlexy-Vits</i>)

Alteration – Note

10565C	ACLIDINIUM + FORMOTEROL (EFORMOTEROL) , acclidinium 340 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations (<i>Brimica Genuair</i>)
8961P	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL syringes (<i>Humira</i>)
8962Q	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges (<i>Humira</i>)
8963R	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (<i>Humira</i>)
8964T	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (<i>Humira</i>)
8965W	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges (<i>Humira</i>)
8966X	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges (<i>Humira</i>)
10018G	BUDESONIDE + FORMOTEROL (EFORMOTEROL) , budesonide 200 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation pressurised inhalation, 120 actuations (<i>Symbicort Rapihaler 200/6</i>)
11301T	BUDESONIDE + FORMOTEROL (EFORMOTEROL) , budesonide 400 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 2 x 60 actuations (<i>DuoResp Spiromax</i>)
8750M	BUDESONIDE + FORMOTEROL (EFORMOTEROL) , budesonide 400 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 2 x 60 actuations (<i>Symbicort Turbuhaler 400/12</i>)
8519J	FLUTICASONE + SALMETEROL , fluticasone propionate 250 microgram/actuation + salmeterol 25 microgram/actuation pressurised inhalation, 120 actuations (<i>Fluticasone + Salmeterol Cipla 250/25, SalplusF Inhaler 250/25, Seretide MDI 250/25</i>)
8432T	FLUTICASONE + SALMETEROL , fluticasone propionate 500 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations (<i>Seretide Accuhaler 500/50</i>)
11124L	FLUTICASONE FUROATE + VILANTEROL , fluticasone furoate 100 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations (<i>Breo Ellipta 100/25</i>)
10156M	INDACATEROL + GLYCOPYRRONIUM , indacaterol 110 microgram + glycopyrronium 50 microgram powder for inhalation, 30 capsules (<i>ultibro breezhaler 110/50</i>)
11037X	PEGINTERFERON ALFA-2A , peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes (<i>Pegasys</i>)
10557P	TIOTROPIUM + OLODATEROL , tiotropium 2.5 microgram/actuation + olodaterol 2.5 microgram/actuation inhalation solution, 60 actuations (<i>Spiolto Respimat</i>)
10188F	UMECLIDINIUM + VILANTEROL , umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations (<i>Anoro Ellipta 62.5/25</i>)

Alteration – Restriction

10565C	ACLIDINIUM + FORMOTEROL (EFORMOTEROL) , acclidinium 340 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations (<i>Brimica Genuair</i>)
11382C	GOLIMUMAB , golimumab 100 mg/mL injection, 1 mL injection device (<i>Simponi</i>)
11213E	IBRUTINIB , ibrutinib 140 mg capsule, 90 (<i>Imbruvica</i>)

10156M	INDACATEROL + GLYCOPYRRONIUM , indacaterol 110 microgram + glycopyrronium 50 microgram powder for inhalation, 30 capsules (<i>ultibro breezhaler 110/50</i>)
8628D	MONTelukAST , montelukast 5 mg chewable tablet, 28 (<i>APO-Montelukast, Auro-Montelukast Tabs 5, Chem mart Montelukast, Lukair, Montelukast AN, Montelukast GH, Montelukast Sandoz 5, Respikast 5, Singulair, Terry White Chemists Montelukast</i>)
11037X	PEGINTERFERON ALFA-2A , peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes (<i>Pegasys</i>)
10557P	TIOTROPIUM + OLODATEROL , tiotropium 2.5 microgram/actuation + olodaterol 2.5 microgram/actuation inhalation solution, 60 actuations (<i>Spiolto Respimat</i>)
10188F	UMECLIDINIUM + VILANTEROL , umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations (<i>Anoro Ellipta 62.5/25</i>)

Alteration – Restriction Level

		From	To
10024N	BUDESONIDE + FORMOTEROL (EFORMOTEROL) , budesonide 50 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 3 microgram/actuation pressurised inhalation, 120 actuations (<i>Symbicort Rapihaler 50/3</i>)	restricted	streamlined
10015D	BUDESONIDE + FORMOTEROL (EFORMOTEROL) , budesonide 100 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 3 microgram/actuation pressurised inhalation, 120 actuations (<i>Symbicort Rapihaler 100/3</i>)	restricted	streamlined
10018G	BUDESONIDE + FORMOTEROL (EFORMOTEROL) , budesonide 200 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation pressurised inhalation, 120 actuations (<i>Symbicort Rapihaler 200/6</i>)	restricted	streamlined
8796Y	BUDESONIDE + FORMOTEROL (EFORMOTEROL) , budesonide 100 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations (<i>Symbicort Turbuhaler 100/6</i>)	restricted	streamlined
11273H	BUDESONIDE + FORMOTEROL (EFORMOTEROL) , budesonide 200 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations (<i>DuoResp Spiromax</i>)	restricted	streamlined
8625Y	BUDESONIDE + FORMOTEROL (EFORMOTEROL) , budesonide 200 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations (<i>Symbicort Turbuhaler 200/6</i>)	restricted	streamlined
11301T	BUDESONIDE + FORMOTEROL (EFORMOTEROL) , budesonide 400 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 2 x 60 actuations (<i>DuoResp Spiromax</i>)	restricted	streamlined
8750M	BUDESONIDE + FORMOTEROL (EFORMOTEROL) , budesonide 400 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 2 x 60 actuations (<i>Symbicort Turbuhaler 400/12</i>)	restricted	streamlined
2827T	FLUTICASONE + FORMOTEROL (EFORMOTEROL) , fluticasone propionate 50 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 5 microgram/actuation pressurised inhalation, 120 actuations (<i>flutiform 50/5</i>)	restricted	streamlined
10007Q	FLUTICASONE + FORMOTEROL (EFORMOTEROL) , fluticasone propionate 125 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 5 microgram/actuation pressurised inhalation, 120 actuations (<i>flutiform 125/5</i>)	restricted	streamlined
10008R	FLUTICASONE + FORMOTEROL (EFORMOTEROL) , fluticasone propionate 250 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 10 microgram/actuation pressurised inhalation, 120 actuations (<i>flutiform 250/10</i>)	restricted	streamlined
8517G	FLUTICASONE + SALMETEROL , fluticasone propionate 50 microgram/actuation + salmeterol 25 microgram/actuation pressurised inhalation, 120 actuations (<i>Seretide MDI 50/25</i>)	restricted	streamlined
8518H	FLUTICASONE + SALMETEROL , fluticasone propionate 125 microgram/actuation + salmeterol 25 microgram/actuation pressurised inhalation, 120 actuations (<i>Fluticasone + Salmeterol Cipla 125/25, SalplusF Inhaler 125/25, Seretide MDI 125/25</i>)	restricted	streamlined
8519J	FLUTICASONE + SALMETEROL , fluticasone propionate 250 microgram/actuation + salmeterol 25 microgram/actuation pressurised inhalation, 120 actuations (<i>Fluticasone + Salmeterol Cipla 250/25, SalplusF Inhaler 250/25, Seretide MDI 250/25</i>)	restricted	streamlined

8430Q	FLUTICASONE + SALMETEROL , fluticasone propionate 100 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations (<i>Seretide Accuhaler 100/50</i>)	restricted	streamlined
8431R	FLUTICASONE + SALMETEROL , fluticasone propionate 250 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations (<i>Seretide Accuhaler 250/50</i>)	restricted	streamlined
8432T	FLUTICASONE + SALMETEROL , fluticasone propionate 500 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations (<i>Seretide Accuhaler 500/50</i>)	restricted	streamlined
11124L	FLUTICASONE FUROATE + VILANTEROL , fluticasone furoate 100 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations (<i>Breo Ellipta 100/25</i>)	restricted	streamlined
11129R	FLUTICASONE FUROATE + VILANTEROL , fluticasone furoate 200 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations (<i>Breo Ellipta 200/25</i>)	restricted	streamlined
11037X	PEGINTERFERON ALFA-2A , peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes (<i>Pegasys</i>)	authority-required	unrestricted

Alteration – Manufacturer Code

		<i>From</i>	<i>To</i>
2413B	<i>Frusemide-Clarix</i> – FUROSEMIDE (FRUSEMIDE) , furosemide (frusemide) 20 mg/2 mL injection, 5 x 2 mL ampoules	AE	BX
8707G	<i>Eligard 1 month</i> – LEUPRORELIN , leuporelin acetate 7.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack	TL	MF
8708H	<i>Eligard 3 month</i> – LEUPRORELIN , leuporelin acetate 22.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack	TL	MF
8709J	<i>Eligard 4 month</i> – LEUPRORELIN , leuporelin acetate 30 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack	TL	MF
8859G	<i>Eligard 6 month</i> – LEUPRORELIN , leuporelin acetate 45 mg injection: modified release [1] (&) inert substance diluent [1 syringe], 1 pack	TL	MF
10962Y	<i>Bi ELIGARD CP</i> – LEUPRORELIN (&) INERT SUBSTANCE (&) BICALUTAMIDE , leuporelin acetate 7.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe] (&) bicalutamide 50 mg tablet [28], 1 pack	TL	MF
10963B	<i>Bi ELIGARD CP</i> – LEUPRORELIN (&) INERT SUBSTANCE (&) BICALUTAMIDE , leuporelin acetate 22.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe] (&) bicalutamide 50 mg tablet [28], 1 pack	TL	MF
10969H	<i>Bi ELIGARD CP</i> – LEUPRORELIN (&) INERT SUBSTANCE (&) BICALUTAMIDE , leuporelin acetate 22.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe] (&) bicalutamide 50 mg tablet [84], 1 pack	TL	MF

Alteration – Number of Repeats

		<i>From</i>	<i>To</i>
11382C	GOLIMUMAB , golimumab 100 mg/mL injection, 1 mL injection device (<i>Simponi</i>)	1	4
11037X	PEGINTERFERON ALFA-2A , peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes (<i>Pegasys</i>)	2	5

Advance Notices

1 September 2018

Deletion – Brand

1007B	<i>Ozvir, RA</i> – ACICLOVIR , aciclovir 200 mg tablet, 90
9012H	<i>Terry White Chemists Alendronate Plus D3 70 mg/70 mcg, TW</i> – ALENDRONATE + COLECALCIFEROL , alendronate 70 mg + colecalciferol 70 microgram tablet, 4
9012H	<i>Chem mart Alendronate Plus D3 70 mg/70 mcg, CH</i> – ALENDRONATE + COLECALCIFEROL , alendronate 70 mg + colecalciferol 70 microgram tablet, 4
9183H	<i>Terry White Chemists Alendronate Plus D3 70 mg/140 mcg, TW</i> – ALENDRONATE + COLECALCIFEROL , alendronate 70 mg + colecalciferol 140 microgram (5600 units) tablet, 4
9183H	<i>Chem mart Alendronate Plus D3 70 mg/140 mcg, CH</i> – ALENDRONATE + COLECALCIFEROL , alendronate 70 mg + colecalciferol 140 microgram (5600 units) tablet, 4

2600W Chem mart Allopurinol, CH – **ALLOPURINOL**, allopurinol 100 mg tablet, 200

2600W Terry White Chemists Allopurinol, TW – **ALLOPURINOL**, allopurinol 100 mg tablet, 200

2604C Chem mart Allopurinol, CH – **ALLOPURINOL**, allopurinol 300 mg tablet, 60

2604C Terry White Chemists Allopurinol, TW – **ALLOPURINOL**, allopurinol 300 mg tablet, 60

2130D Kalma 0.25, AF – **ALPRAZOLAM**, alprazolam 250 microgram tablet, 50

2131E Kalma 0.5, AF – **ALPRAZOLAM**, alprazolam 500 microgram tablet, 50

2132F Kalma 1, AF – **ALPRAZOLAM**, alprazolam 1 mg tablet, 50

8213G Atorvastatin SCP 10, RZ – **ATORVASTATIN**, atorvastatin 10 mg tablet, 30

8214H Atorvastatin SCP 20, RZ – **ATORVASTATIN**, atorvastatin 20 mg tablet, 30

8215J Atorvastatin SCP 40, RZ – **ATORVASTATIN**, atorvastatin 40 mg tablet, 30

8521L Atorvastatin SCP 80, RZ – **ATORVASTATIN**, atorvastatin 80 mg tablet, 30

9230T Atorvastatin SCP 10, RZ – **ATORVASTATIN**, atorvastatin 10 mg tablet, 30

9231W Atorvastatin SCP 20, RZ – **ATORVASTATIN**, atorvastatin 20 mg tablet, 30

9232X Atorvastatin SCP 40, RZ – **ATORVASTATIN**, atorvastatin 40 mg tablet, 30

9233Y Atorvastatin SCP 80, RZ – **ATORVASTATIN**, atorvastatin 80 mg tablet, 30

8255L Chem mart Carvedilol 3.125 mg, CH – **CARVEDILOL**, carvedilol 3.125 mg tablet, 30

8255L Terry White Chemists Carvedilol 3.125 mg, TW – **CARVEDILOL**, carvedilol 3.125 mg tablet, 30

8256M Chem mart Carvedilol 6.25 mg, CH – **CARVEDILOL**, carvedilol 6.25 mg tablet, 60

8256M Terry White Chemists Carvedilol 6.25 mg, TW – **CARVEDILOL**, carvedilol 6.25 mg tablet, 60

8257N Chem mart Carvedilol 12.5 mg, CH – **CARVEDILOL**, carvedilol 12.5 mg tablet, 60

8257N Terry White Chemists Carvedilol 12.5 mg, TW – **CARVEDILOL**, carvedilol 12.5 mg tablet, 60

8258P Chem mart Carvedilol 25 mg, CH – **CARVEDILOL**, carvedilol 25 mg tablet, 60

8258P Terry White Chemists Carvedilol 25 mg, TW – **CARVEDILOL**, carvedilol 25 mg tablet, 60

10781K Terry White Chemists Doxycycline, TW – **DOXYCYCLINE**, doxycycline 100 mg tablet, 7

10781K Chem mart Doxycycline, CH – **DOXYCYCLINE**, doxycycline 100 mg tablet, 7

5082L Terry White Chemists Doxycycline, TW – **DOXYCYCLINE**, doxycycline 100 mg tablet, 7

5082L Chem mart Doxycycline, CH – **DOXYCYCLINE**, doxycycline 100 mg tablet, 7

9105F Terry White Chemists Doxycycline, TW – **DOXYCYCLINE**, doxycycline 100 mg tablet, 7

9105F Chem mart Doxycycline, CH – **DOXYCYCLINE**, doxycycline 100 mg tablet, 7

9106G Terry White Chemists Doxycycline, TW – **DOXYCYCLINE**, doxycycline 50 mg tablet, 25

9106G Chem mart Doxycycline, CH – **DOXYCYCLINE**, doxycycline 50 mg tablet, 25

9107H Terry White Chemists Doxycycline, TW – **DOXYCYCLINE**, doxycycline 100 mg tablet, 7

9107H Chem mart Doxycycline, CH – **DOXYCYCLINE**, doxycycline 100 mg tablet, 7

9108J Terry White Chemists Doxycycline, TW – **DOXYCYCLINE**, doxycycline 100 mg tablet, 7

9108J Chem mart Doxycycline, CH – **DOXYCYCLINE**, doxycycline 100 mg tablet, 7

2449X Chem mart Glliclazide, CH – **GLICLAZIDE**, gliclazide 80 mg tablet, 100

2449X Terry White Chemists Glliclazide, TW – **GLICLAZIDE**, gliclazide 80 mg tablet, 100

5552F Chem mart Latanoprost, CH – **LATANOPROST**, latanoprost 0.005% eye drops, 2.5 mL

5552F Terry White Chemists Latanoprost, TW – **LATANOPROST**, latanoprost 0.005% eye drops, 2.5 mL

8243W Chem mart Latanoprost, CH – **LATANOPROST**, latanoprost 0.005% eye drops, 2.5 mL

8243W Terry White Chemists Latanoprost, TW – **LATANOPROST**, latanoprost 0.005% eye drops, 2.5 mL

8534E Lercanidipine GH, GQ – **LERCANIDIPINE**, lercanidipine hydrochloride 10 mg tablet, 28

8245Y Letrozole RBX, RA – **LETROZOLE**, letrozole 2.5 mg tablet, 30

2456G Chem mart Lisinopril, CH – **LISINOPRIL**, lisinopril 5 mg tablet, 30

2456G	<i>Terry White Chemists Lisinopril, TW</i> – LISINOPRIL , lisinopril 5 mg tablet, 30
2457H	<i>Chem mart Lisinopril, CH</i> – LISINOPRIL , lisinopril 10 mg tablet, 30
2457H	<i>Terry White Chemists Lisinopril, TW</i> – LISINOPRIL , lisinopril 10 mg tablet, 30
2458J	<i>Chem mart Lisinopril, CH</i> – LISINOPRIL , lisinopril 20 mg tablet, 30
2458J	<i>Terry White Chemists Lisinopril, TW</i> – LISINOPRIL , lisinopril 20 mg tablet, 30
8627C	<i>Terry White Chemists Montelukast, TW</i> – MONTELUKAST , montelukast 4 mg chewable tablet, 28
8627C	<i>Chem mart Montelukast, CH</i> – MONTELUKAST , montelukast 4 mg chewable tablet, 28
8628D	<i>Terry White Chemists Montelukast, TW</i> – MONTELUKAST , montelukast 5 mg chewable tablet, 28
8628D	<i>Chem mart Montelukast, CH</i> – MONTELUKAST , montelukast 5 mg chewable tablet, 28
8449Q	<i>Chem mart Perindopril/ Indapamide 4/1.25, CH</i> – PERINDOPRIL + INDAPAMIDE , perindopril erbumine 4 mg + indapamide hemihydrate 1.25 mg tablet, 30
8449Q	<i>Terry White Chemists Perindopril/ Indapamide 4/1.25, TW</i> – PERINDOPRIL + INDAPAMIDE , perindopril erbumine 4 mg + indapamide hemihydrate 1.25 mg tablet, 30
2833D	<i>Chem mart Pravastatin, CH</i> – PRAVASTATIN , pravastatin sodium 10 mg tablet, 30
2833D	<i>Terry White Chemists Pravastatin, TW</i> – PRAVASTATIN , pravastatin sodium 10 mg tablet, 30
2834E	<i>Chem mart Pravastatin, CH</i> – PRAVASTATIN , pravastatin sodium 20 mg tablet, 30
2834E	<i>Terry White Chemists Pravastatin, TW</i> – PRAVASTATIN , pravastatin sodium 20 mg tablet, 30
8197K	<i>Chem mart Pravastatin, CH</i> – PRAVASTATIN , pravastatin sodium 40 mg tablet, 30
8197K	<i>Terry White Chemists Pravastatin, TW</i> – PRAVASTATIN , pravastatin sodium 40 mg tablet, 30
8829Q	<i>Terry White Chemists Pravastatin, TW</i> – PRAVASTATIN , pravastatin sodium 80 mg tablet, 30
8829Q	<i>Chem mart Pravastatin, CH</i> – PRAVASTATIN , pravastatin sodium 80 mg tablet, 30
9237E	<i>Chem mart Pravastatin, CH</i> – PRAVASTATIN , pravastatin sodium 10 mg tablet, 30
9237E	<i>Terry White Chemists Pravastatin, TW</i> – PRAVASTATIN , pravastatin sodium 10 mg tablet, 30
9238F	<i>Chem mart Pravastatin, CH</i> – PRAVASTATIN , pravastatin sodium 20 mg tablet, 30
9238F	<i>Terry White Chemists Pravastatin, TW</i> – PRAVASTATIN , pravastatin sodium 20 mg tablet, 30
9239G	<i>Chem mart Pravastatin, CH</i> – PRAVASTATIN , pravastatin sodium 40 mg tablet, 30
9239G	<i>Terry White Chemists Pravastatin, TW</i> – PRAVASTATIN , pravastatin sodium 40 mg tablet, 30
9240H	<i>Terry White Chemists Pravastatin, TW</i> – PRAVASTATIN , pravastatin sodium 80 mg tablet, 30
9240H	<i>Chem mart Pravastatin, CH</i> – PRAVASTATIN , pravastatin sodium 80 mg tablet, 30
1478T	<i>Terry White Chemists Prazosin, TW</i> – PRAZOSIN , prazosin 5 mg tablet, 100
1478T	<i>Chem mart Prazosin, CH</i> – PRAZOSIN , prazosin 5 mg tablet, 100
1479W	<i>Terry White Chemists Prazosin, TW</i> – PRAZOSIN , prazosin 1 mg tablet, 100
1479W	<i>Chem mart Prazosin, CH</i> – PRAZOSIN , prazosin 1 mg tablet, 100
1480X	<i>Terry White Chemists Prazosin, TW</i> – PRAZOSIN , prazosin 2 mg tablet, 100
1480X	<i>Chem mart Prazosin, CH</i> – PRAZOSIN , prazosin 2 mg tablet, 100

1 October 2018

Deletion – Brand

8754R	<i>Neocate Advance, SB</i> – AMINO ACID SYNTHETIC FORMULA , amino acid synthetic formula powder for oral liquid, 400 g
8755T	<i>Neocate Advance, SB</i> – AMINO ACID SYNTHETIC FORMULA , amino acid synthetic formula powder for oral liquid, 400 g
5276Q	<i>Daivobet 50/500 gel, LO</i> – CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE , calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% gel, 30 g
10050Y	<i>basecal 100, VF</i> – CARBOHYDRATES, FAT, VITAMINS, MINERALS, TRACE ELEMENTS AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID , carbohydrates, fat, vitamins, minerals, trace elements and supplemented with arachidonic acid and docosahexaenoic acid providing 100 kilocalories powder for oral liquid, 30 x 21.5 g sachets

5509Y	<i>TheraTears, CX</i> – CARMELLOSE SODIUM , carmellose sodium 0.25% (1.5 mg/0.6 mL) eye drops, 24 x 0.6 mL unit doses
5510B	<i>TheraTears, CX</i> – CARMELLOSE SODIUM , carmellose sodium 1% (6 mg/0.6 mL) eye gel, 28 x 0.6 mL unit doses
8823J	<i>TheraTears, CX</i> – CARMELLOSE SODIUM , carmellose sodium 0.25% (1.5 mg/0.6 mL) eye drops, 24 x 0.6 mL unit doses
8824K	<i>TheraTears, CX</i> – CARMELLOSE SODIUM , carmellose sodium 1% (6 mg/0.6 mL) eye gel, 28 x 0.6 mL unit doses
3138E	<i>Cleocin, FZ</i> – CLINDAMYCIN , clindamycin 150 mg capsule, 24
5057E	<i>Cleocin, FZ</i> – CLINDAMYCIN , clindamycin 150 mg capsule, 24
10026Q	<i>Endoxan, BX</i> – CYCLOPHOSPHAMIDE , cyclophosphamide 50 mg tablet, 50
2975N	<i>Aptamil Gold+ De-Lact, NU</i> – MILK POWDER LACTOSE FREE FORMULA PREDIGESTED , milk powder lactose free formula predigested powder for oral liquid, 900 g
8370M	<i>ReVia, BQ</i> – NALTREXONE , naltrexone hydrochloride 50 mg tablet, 30
1671Y	<i>Deca-Durabolin, AS</i> – NANDROLONE DECANOATE , nandrolone decanoate 50 mg/mL injection, 1 mL syringe
8508T	<i>Rabeprazole generichealth, GQ</i> – RABEPRAZOLE , rabeprazole sodium 20 mg enteric tablet, 30
8509W	<i>Rabeprazole generichealth, GQ</i> – RABEPRAZOLE , rabeprazole sodium 20 mg enteric tablet, 30
5546X	<i>Nyogel, AS</i> – TIMOLOL , timolol 0.1% eye gel, 5 g
8803H	<i>Nyogel, AS</i> – TIMOLOL , timolol 0.1% eye gel, 5 g

1 December 2018

Deletion – Brand

8362D	<i>Xeloda, RO</i> – CAPECITABINE , capecitabine 500 mg tablet, 120
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Highly Specialised Drugs Program (Private Hospital)

Additions

Addition – Item

11420C	BACLOFEN , baclofen 10 mg/5 mL intrathecal injection, 5 x 5 mL ampoules (<i>Bacethecal</i>)
11415T	CLOZAPINE , clozapine 50 mg/mL oral liquid, 100 mL (<i>Versacloz</i>)
11337Q	GLECAPREVIR + PIBRENTASVIR , glecaprevir 100 mg + pibrentasvir 40 mg film-coated tablet, 84 (<i>Maviret</i>)
11346E	GLECAPREVIR + PIBRENTASVIR , glecaprevir 100 mg + pibrentasvir 40 mg film-coated tablet, 84 (<i>Maviret</i>)
11355P	GLECAPREVIR + PIBRENTASVIR , glecaprevir 100 mg + pibrentasvir 40 mg film-coated tablet, 84 (<i>Maviret</i>)
11412P	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Remicade</i>)
11432Q	INFLIXIMAB , infliximab 100 mg injection, 1 vial (<i>Inflixtra, Renflexis</i>)

Deletions

Deletion – Note

11405G	ZOLEDRONIC ACID , zoledronic acid 4 mg/5 mL injection, 5 x 5 mL vials (<i>Clarix Lifesciences Zoledronic Acid</i>)
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Alterations

Alteration – Item Description

From

6249X	DOXORUBICIN HYDROCHLORIDE-PEGYLATED LIPOSOMAL , doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial (<i>Caelyx, Liposomal Doxorubicin SUN</i>)
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To

6249X	DOXORUBICIN HYDROCHLORIDE (AS PEGYLATED LIPOSOMAL) , doxorubicin hydrochloride (as pegylated liposomal) 20 mg/10 mL injection, 10 mL vial (<i>Caelyx, Liposomal Doxorubicin SUN</i>)
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From

9641K	ETANERCEPT , ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (<i>Enbrel</i>)
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To

9641K	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL injection devices (<i>Enbrel</i>)
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From

9615C	ETANERCEPT , ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (<i>Enbrel</i>)
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To

9615C	ETANERCEPT , etanercept 50 mg/mL injection, 4 x 1 mL syringes (<i>Enbrel</i>)
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Alteration – Note

- 11128Q **BACLOFEN**, baclofen 10 mg/5 mL intrathecal injection, 10 x 5 mL ampoules (*Sintetica Baclofen Intrathecal*)
- 6284R **BACLOFEN**, baclofen 10 mg/5 mL intrathecal injection, 5 mL ampoule (*Bacthecal, Lioresal Intrathecal*)
- 9674E **INFLIXIMAB**, infliximab 100 mg injection, 1 vial (*Inflixtra, Remicade, Renflexis*)

Alteration – Restriction

- 9674E **INFLIXIMAB**, infliximab 100 mg injection, 1 vial (*Inflixtra, Remicade, Renflexis*)
- 9642L **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 (*Revlimid*)
- 9643M **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 (*Revlimid*)
- 9644N **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 (*Revlimid*)
- 9645P **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21 (*Revlimid*)
- 6363X **PEGFILGRASTIM**, pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe (*Neulasta, Ristempa*)
- 10417G **POMALIDOMIDE**, pomalidomide 3 mg capsule, 21 (*Pomalyst*)
- 10386P **POMALIDOMIDE**, pomalidomide 4 mg capsule, 21 (*Pomalyst*)

Highly Specialised Drugs Program (Public Hospital)

Additions

Addition – Item

- 11421D **BACLOFEN**, baclofen 10 mg/5 mL intrathecal injection, 5 x 5 mL ampoules (*Bacthecal*)
- 11433R **CLOZAPINE**, clozapine 50 mg/mL oral liquid, 100 mL (*Versacloz*)
- 11332K **GLECAPREVIR + PIBRENTASVIR**, glecaprevir 100 mg + pibrentasvir 40 mg film-coated tablet, 84 (*Maviret*)
- 11333L **GLECAPREVIR + PIBRENTASVIR**, glecaprevir 100 mg + pibrentasvir 40 mg film-coated tablet, 84 (*Maviret*)
- 11345D **GLECAPREVIR + PIBRENTASVIR**, glecaprevir 100 mg + pibrentasvir 40 mg film-coated tablet, 84 (*Maviret*)
- 11423F **INFLIXIMAB**, infliximab 100 mg injection, 1 vial (*Inflixtra, Renflexis*)
- 11424G **INFLIXIMAB**, infliximab 100 mg injection, 1 vial (*Remicade*)

Addition – Note

- 11370K **NUSINERSEN**, nusinersen 12 mg/5 mL injection, 5 mL vial (*Spinraza*)

Deletions

Deletion – Note

- 11388J **ZOLEDRONIC ACID**, zoledronic acid 4 mg/5 mL injection, 5 x 5 mL vials (*Claris Lifesciences Zoledronic Acid*)

Alterations

Alteration – Item Description

From

- 5705G **DOXORUBICIN HYDROCHLORIDE-PEGYLATED LIPOSOMAL**, doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial (*Caelyx, Liposomal Doxorubicin SUN*)

To

- 5705G **DOXORUBICIN HYDROCHLORIDE (AS PEGYLATED LIPOSOMAL)**, doxorubicin hydrochloride (as pegylated liposomal) 20 mg/10 mL injection, 10 mL vial (*Caelyx, Liposomal Doxorubicin SUN*)

From

- 5735W **ETANERCEPT**, ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (*Enbrel*)

To

- 5735W **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL injection devices (*Enbrel*)

From

- 5733R **ETANERCEPT**, ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (*Enbrel*)

To

- 5733R **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL syringes (*Enbrel*)

Alteration – Note

- 11126N **BACLOFEN**, baclofen 10 mg/5 mL intrathecal injection, 10 x 5 mL ampoules (*Sintetica Baclofen Intrathecal*)
- 5617P **BACLOFEN**, baclofen 10 mg/5 mL intrathecal injection, 5 mL ampoule (*Bacthecal, Lioresal Intrathecal*)

9654D **INFLIXIMAB**, infliximab 100 mg injection, 1 vial (*Inflixtra, Remicade, Renflexis*)

11363C **NUSINERSEN**, nusinersen 12 mg/5 mL injection, 5 mL vial (*Spinraza*)

Alteration – Restriction

9654D **INFLIXIMAB**, infliximab 100 mg injection, 1 vial (*Inflixtra, Remicade, Renflexis*)

5783J **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 (*Revlimid*)

5784K **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 (*Revlimid*)

5785L **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 (*Revlimid*)

5786M **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21 (*Revlimid*)

11363C **NUSINERSEN**, nusinersen 12 mg/5 mL injection, 5 mL vial (*Spinraza*)

11370K **NUSINERSEN**, nusinersen 12 mg/5 mL injection, 5 mL vial (*Spinraza*)

11378W **NUSINERSEN**, nusinersen 12 mg/5 mL injection, 5 mL vial (*Spinraza*)

9514R **PEGFILGRASTIM**, pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe (*Neulasta, Ristempa*)

10406Q **POMALIDOMIDE**, pomalidomide 3 mg capsule, 21 (*Pomalyst*)

10387Q **POMALIDOMIDE**, pomalidomide 4 mg capsule, 21 (*Pomalyst*)

Alteration – Number of Repeats

		From	To
11363C	NUSINERSEN , nusinersen 12 mg/5 mL injection, 5 mL vial (<i>Spinraza</i>)	1	3

Highly Specialised Drugs Program (Community Access)

Additions

Addition – Item

11422E **CLOZAPINE**, clozapine 50 mg/mL oral liquid, 100 mL (*Versacloz*)

Alterations

Alteration – Item Description

From

11104K **EMTRICITABINE + RILPIVIRINE + TENOFOVIR ALAFENAMIDE**, emtricitabine 200 mg + rilpivirine 25 mg + tenofovir alafenamide 25 mg tablet, 30 tablets (*Odefsey*)

To

11104K **EMTRICITABINE + RILPIVIRINE + TENOFOVIR ALAFENAMIDE**, emtricitabine 200 mg + rilpivirine 25 mg + tenofovir alafenamide 25 mg tablet, 30 (*Odefsey*)

From

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

To

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

From

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

To

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

From

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

To

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

Advance Notices

1 October 2018

Deletion – Brand

10274R *Emtriva, GI* – **EMTRICITABINE**, emtricitabine 200 mg capsule, 30

10363K *Crixivan 400 mg, MK* – **INDINAVIR**, indinavir 400 mg capsule, 180

1 November 2018

Deletion – Brand

10278Y *Pegasys, RO* – **PEGINTERFERON ALFA-2A**, peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes

10280C *Pegasys, RO* – **PEGINTERFERON ALFA-2A**, peginterferon alfa-2a 135 microgram/0.5 mL injection, 4 x 0.5 mL syringes

IVF Program

Additions

Addition – Item

11430N **FOLLITROPIN DELTA**, follitropin delta 12 microgram/0.36 mL injection, 0.36 mL injection device (*Rekovele*)
11431P **FOLLITROPIN DELTA**, follitropin delta 36 microgram/1.08 mL injection, 1.08 mL injection device (*Rekovele*)
11414R **FOLLITROPIN DELTA**, follitropin delta 72 microgram/2.16 mL injection, 2.16 mL injection device (*Rekovele*)

Addition – Note

10861P **FOLLITROPIN ALFA**, follitropin alfa 75 units (5.5 microgram)/0.125 mL injection, 5 x 0.125 mL injection devices (*Bemfola*)
10873G **FOLLITROPIN ALFA**, follitropin alfa 150 units (11 microgram)/0.25 mL injection, 5 x 0.25 mL injection devices (*Bemfola*)
10872F **FOLLITROPIN ALFA**, follitropin alfa 225 units (16.5 microgram)/0.375 mL injection, 5 x 0.375 mL injection devices (*Bemfola*)
10866X **FOLLITROPIN ALFA**, follitropin alfa 300 units (22 microgram)/0.5 mL injection, 5 x 0.5 mL injection devices (*Bemfola*)
6431L **FOLLITROPIN ALFA**, follitropin alfa 300 units (21.84 microgram)/0.5 mL injection, 0.5 mL cartridge (*Gonal-f Pen*)
10867Y **FOLLITROPIN ALFA**, follitropin alfa 450 units (33 microgram)/0.75 mL injection, 5 x 0.75 mL injection devices (*Bemfola*)
6432M **FOLLITROPIN ALFA**, follitropin alfa 450 units (32.76 microgram)/0.75 mL injection, 0.75 mL cartridge (*Gonal-f Pen*)
6433N **FOLLITROPIN ALFA**, follitropin alfa 900 units (65.52 microgram)/1.5 mL injection, 1.5 mL cartridge (*Gonal-f Pen*)

Repatriation Pharmaceutical Benefits

Advance Notices

1 September 2018

Deletion – Brand

2194L *Terry White Chemists Alendronate Plus D3 70 mg/70 mcg, TW* – **ALENDRONATE + COLECALCIFEROL**, alendronate 70 mg + colecalciferol 70 microgram tablet, 4
2194L *Chem mart Alendronate Plus D3 70 mg/70 mcg, CH* – **ALENDRONATE + COLECALCIFEROL**, alendronate 70 mg + colecalciferol 70 microgram tablet, 4
2224C *Terry White Chemists Alendronate Plus D3 70 mg/140 mcg, TW* – **ALENDRONATE + COLECALCIFEROL**, alendronate 70 mg + colecalciferol 140 microgram (5600 units) tablet, 4
2224C *Chem mart Alendronate Plus D3 70 mg/140 mcg, CH* – **ALENDRONATE + COLECALCIFEROL**, alendronate 70 mg + colecalciferol 140 microgram (5600 units) tablet, 4
4007X *Sebizole, EA* – **KETOCONAZOLE**, ketoconazole 2% shampoo, 100 mL

1 October 2018

Deletion – Brand

4390C *Wartec Cream, GK* – **PODOPHYLLOTOXIN**, podophyllotoxin 0.15% cream, 5 g
4586J *Silaran, RA* – **SILDENAFIL**, sildenafil 100 mg tablet, 4

General Pharmaceutical Benefits

■ ACLIDINIUM

Note The treatment must not be used in combination with a LAMA/LABA or SAMA

Note A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note A SAMA includes ipratropium

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

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

Restricted benefit

Chronic obstructive pulmonary disease (COPD)

aclidinium 322 microgram/actuation inhalation: powder for, 60 actuations

10124W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	62.21	39.50	Bretaris Genuair [FK]

■ ACLIDINIUM + FORMOTEROL (EFORMOTEROL)

Note This product is not PBS-subsidised for the treatment of asthma.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Note The treatment must not be used in combination with an ICS/LABA, LAMA, LABA, or SAMA

Note A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

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

Note A SAMA includes ipratropium

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

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

Authority required (STREAMLINED)

7798

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); OR
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR
- Patient must have been stabilised on a combination of a LAMA and a LABA.

aclidinium 340 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations

10565C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	87.62	39.50	Brimica Genuair [FK]

■ ADALIMUMAB

Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term "biological medicine" appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS- subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab or infliximab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab or infliximab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab or infliximab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab or infliximab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab or infliximab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab or infliximab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised adalimumab or infliximab therapy after 1 April 2011.

(a) Initial treatment. Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab or infliximab therapy in this treatment cycle and wishes to commence such therapy (Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1); or

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

(iii) a patient wishes to re-commence treatment with adalimumab or infliximab following a break in PBS-subsidised therapy with that agent (Change or Re-commencement of treatment after a break in therapy of less than 5 years (Initial 2)

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

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 biological medicine.

For subsequent courses of PBS-subsidised adalimumab or infliximab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with adalimumab or infliximab, 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 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 supply of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.

A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab or infliximab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

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

(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 submitted with the first authority application for adalimumab or infliximab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note No applications for increased maximum quantities and/or repeats will be authorised.

Authority required

Initial 1

Initial treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

- (a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and
- (b) has an externally draining enterocutaneous or rectovaginal fistula; and
- (c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

Authority applications must be made in writing and must include:

- (a) two completed authority prescription forms; and
- (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and
 - (ii) a signed patient acknowledgement.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum of 16 weeks treatment will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia 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 to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

Authority required

Initial 2

Change or re-commencement of treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with adalimumab of complex refractory fistulising Crohn disease by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

- (a) has a documented history of complex refractory fistulising Crohn disease; and
- (b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or infliximab for a draining enterocutaneous or rectovaginal fistula; and
- (c) has not failed PBS-subsidised therapy with adalimumab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the time frames specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

- (a) two completed authority prescription forms; and
- (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
 - (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum of 16 weeks treatment will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia 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 to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges

8962Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	3606.66	39.50	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

8965W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1269.60	39.50	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

8963R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	1269.60	39.50	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL syringes

8961P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	3606.66	39.50	Humira [VE]

■ ADALIMUMAB

Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term "biological medicine" appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS- subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab or infliximab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab or infliximab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab or infliximab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab or infliximab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab or infliximab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab or infliximab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised adalimumab or infliximab therapy after 1 April 2011.

(a) Initial treatment. Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab or infliximab therapy in this treatment cycle and wishes to commence such therapy (Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1); or

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

(iii) a patient wishes to re-commence treatment with adalimumab or infliximab following a break in PBS-subsidised therapy with that agent (Change or Re-commencement of treatment after a break in therapy of less than 5 years (Initial 2)

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

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 biological medicine.

For subsequent courses of PBS-subsidised adalimumab or infliximab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab.

One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with adalimumab or infliximab, 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 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 supply of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.

A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab or infliximab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

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

(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 submitted with the first authority application for adalimumab or infliximab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note No applications for increased maximum quantities and/or repeats will be authorised.

Authority required

Initial 3 (grandfather)

Initial PBS-subsidised treatment of complex refractory FISTULISING CROHN DISEASE in a patient who has previously received non-PBS-subsidised therapy with adalimumab.

Initial PBS-subsidised supply for continuing treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who satisfies the following criteria:

(a) has a documented history of complex refractory fistulising Crohn disease and was receiving treatment with adalimumab prior to 4 November 2010; and

(b) had a draining enterocutaneous or rectovaginal fistula(e) prior to commencing treatment with adalimumab; and

(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) is receiving treatment with adalimumab at the time of application; and

(e) has demonstrated or sustained an adequate response to treatment with adalimumab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to adalimumab treatment is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current and baseline Fistula Assessment form including the date of assessment of the patient's condition; and

(ii) a signed patient acknowledgement.

The current fistula assessment must be no more than 1 month old at the time of application.

The baseline fistula assessment must be from immediately prior to commencing treatment with adalimumab.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

A maximum of 24 weeks treatment will be approved under this criterion.

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

Authority required

Continuing treatment of complex refractory FISTULISING CROHN DISEASE.

Continuing PBS-subsidised treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of complex refractory fistulising Crohn disease; and

(b) has demonstrated or sustained an adequate response to treatment with adalimumab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The fistula assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with adalimumab, an assessment of the patient's response must be made following a minimum of 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

Patients are eligible to receive continuing adalimumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

A maximum of 24 weeks treatment will be authorised under this criterion.

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

8966X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1269.60	39.50	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

8964T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1269.60	39.50	Humira [VE]

■ BUDESONIDE + FORMOTEROL (EFORMOTEROL)

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

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

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

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

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

Authority required (STREAMLINED)

4380

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

Population criteria:

- Patient must be aged 12 years or over.

budesonide 100 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations

8796Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	47.91	39.50	Symbicort Turbuhaler 100/6 [AP]

▪ **BUDESONIDE + FORMOTEROL (EFORMOTEROL)**

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

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

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

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

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

Authority required (STREAMLINED)

4397

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist.

Population criteria:

- Patient must be aged 12 years or over.

budesonide 50 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 3 microgram/actuation pressurised inhalation, 120 actuations

10024N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*46.09	39.50	Symbicort Rapihaler 50/3 [AP]

budesonide 100 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 3 microgram/actuation pressurised inhalation, 120 actuations

10015D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*49.31	39.50	Symbicort Rapihaler 100/3 [AP]

▪ **BUDESONIDE + FORMOTEROL (EFORMOTEROL)**

Note Pharmaceutical benefits that have the brand DuoResp Spiromax 200/6 powder for inhalation, 120 actuations and pharmaceutical benefits that have the brand Symbicort Turbuhaler 200/6 powder for inhalation, 120 actuations are equivalent for the purposes of substitution.

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

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

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

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

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

Authority required (STREAMLINED)

7527

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

Population criteria:

- Patient must be aged 18 years or older.

budesonide 200 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations

11273H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	44.64	39.50	^a DuoResp Spiromax [TB]

▪ **BUDESONIDE + FORMOTEROL (EFORMOTEROL)**

Note Pharmaceutical benefits that have the brand DuoResp Spiromax 200/6 powder for inhalation, 120 actuations and pharmaceutical benefits that have the brand Symbicort Turbuhaler 200/6 powder for inhalation, 120 actuations are equivalent for the purposes of substitution.

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

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

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

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

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

Authority required (STREAMLINED)

4380

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

Population criteria:

- Patient must be aged 12 years or over.

budesonide 200 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations

8625Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	44.64	39.50	^a Symbicort Turbuhaler 200/6 [AP]

▪ **BUDESONIDE + FORMOTEROL (EFORMOTEROL)**

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

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

Authority required (STREAMLINED)

4404

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:

- Patient must be aged 12 years or over.

Note Unlike Symbicort Turbuhaler 200/6, Symbicort Rapihaler 200/6 is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy as the approved Product Information does not specify such use.

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

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

Authority required (STREAMLINED)

4689

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy, **AND**
- Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- The treatment must be for symptomatic treatment.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Note The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

Note A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

budesonide 200 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation pressurised inhalation, 120 actuations

10018G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*71.27	39.50	Symbicort Rapihaler 200/6 [AP]

▪ **BUDESONIDE + FORMOTEROL (EFORMOTEROL)**

Note Pharmaceutical benefits that have the brand DuoResp Spiromax 400/12 powder for inhalation, 2 x 60 actuations and pharmaceutical benefits that have the brand Symbicort Turbuhaler 400/12 powder for inhalation, 2 x 60 actuations are equivalent for the purposes of substitution.

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

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

Authority required (STREAMLINED)**7527**

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

Population criteria:

- Patient must be aged 18 years or older.

Note DuoResp Spiromax 400/12 is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.**Note** This product is not indicated for the initiation of treatment in asthma**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Authority required (STREAMLINED)**7574**

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy, **AND**
- Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- The treatment must be for symptomatic treatment.

Population criteria:

- Patient must be aged 18 years or older.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.**Note** The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

budesonide 400 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 2 x 60 actuations

11301T

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
±1	5	..	63.91	39.50	^a DuoResp Spiromax [TB]

■ BUDESONIDE + FORMOTEROL (EFORMOTEROL)**Note** Pharmaceutical benefits that have the brand DuoResp Spiromax 400/12 powder for inhalation, 2 x 60 actuations and pharmaceutical benefits that have the brand Symbicort Turbuhaler 400/12 powder for inhalation, 2 x 60 actuations are equivalent for the purposes of substitution.**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)**4394**

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:

- Patient must be aged 12 years or over.

Note Symbicort 400/12 is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.**Note** This product is not indicated for the initiation of treatment in asthma**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Authority required (STREAMLINED)**4689**

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy, **AND**
- Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- The treatment must be for symptomatic treatment.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.**Note** The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

budesonide 400 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 2 x 60 actuations

8750M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	63.91	39.50	^a Symbicort Turbuhaler 400/12 [AP]

▪ **EZETIMIBE**

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)

5563

Homozygous sitosterolaemia

ezetimibe 10 mg tablet, 30

11408K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	42.98	39.50	^a APO-Ezetimibe [TX]	^a Blooms The Chemist Ezetimibe [IB]
						^a EZEMICHOL [RW]	^a Ezetrol [MK]
						^a Pharmacor Ezetimibe 10 [CR]	^a Zient 10mg [AF]

▪ **FLUTICASONE + FORMOTEROL (EFORMOTEROL)**

Note Flutiform is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

Note Flutiform is not indicated or PBS-subsidised for bronchodilator therapy in COPD.

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

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

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

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

Authority required (STREAMLINED)

4395

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:

- Patient must be aged 12 years or over.

fluticasone propionate 125 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 5 microgram/actuation pressurised inhalation, 120 actuations

10007Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	45.01	39.50	flutiform 125/5 [MF]

fluticasone propionate 250 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 10 microgram/actuation pressurised inhalation, 120 actuations

10008R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	59.92	39.50	flutiform 250/10 [MF]

fluticasone propionate 50 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 5 microgram/actuation pressurised inhalation, 120 actuations

2827T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	37.15	38.38	flutiform 50/5 [MF]

▪ **FLUTICASONE + SALMETEROL**

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

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

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

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

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

Authority required (STREAMLINED)

4930

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:

- Patient must be aged 4 years or older.

fluticasone propionate 250 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations

8431R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	48.49	39.50	Seretide Accuhaler 250/50 [GK]

fluticasone propionate 125 microgram/actuation + salmeterol 25 microgram/actuation pressurised inhalation, 120 actuations

8518H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	‡1	5	..	48.49	39.50	^a Fluticasone + Salmeterol Cipla 125/25 [LR]	^a SalplusF Inhaler 125/25 [YC]
						^a Seretide MDI 125/25 [GK]	

fluticasone propionate 50 microgram/actuation + salmeterol 25 microgram/actuation pressurised inhalation, 120 actuations

8517G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	41.80	39.50	Seretide MDI 50/25 [GK]

fluticasone propionate 100 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations

8430Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	41.80	39.50	Seretide Accuhaler 100/50 [GK]

■ FLUTICASONE + SALMETEROL

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

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

Authority required (STREAMLINED)

4930

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:

- Patient must be aged 4 years or older.

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

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

Authority required (STREAMLINED)

4689

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy, **AND**

- Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**

- The treatment must be for symptomatic treatment.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Note The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

Note A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

fluticasone propionate 250 microgram/actuation + salmeterol 25 microgram/actuation pressurised inhalation, 120 actuations

8519J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	‡1	5	..	61.63	39.50	^a Fluticasone + Salmeterol Cipla 250/25 [LR]	^a SalplusF Inhaler 250/25 [YC]
						^a Seretide MDI 250/25 [GK]	

fluticasone propionate 500 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations

8432T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	61.63	39.50	Seretide Accuhaler 500/50 [GK]

■ FLUTICASONE FUROATE + VILANTEROL

Note This drug is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

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

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

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

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

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

Authority required (STREAMLINED)

4731

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:

- Patient must be aged 12 years or over.

fluticasone furoate 200 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations

11129R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	71.86	39.50	Breo Ellipta 200/25 [GK]

■ FLUTICASONE FUROATE + VILANTEROL

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

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

Authority required (STREAMLINED)

4711

Asthma

Clinical criteria:

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:

- Patient must be aged 12 years or over.

Note This drug is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

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

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

Authority required (STREAMLINED)

4689

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy, **AND**
- Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- The treatment must be for symptomatic treatment.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Note The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

Note A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

fluticasone furoate 100 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations

11124L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	56.36	39.50	Breo Ellipta 100/25 [GK]

■ FOLLITROPIN ALFA

Note Biosimilar prescribing policy Prescribing of the biosimilar brand, Bemfola, is encouraged for treatment naive patients.

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

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

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

Restricted benefit

Anovulatory infertility

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

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

Restricted benefit

Infertility

Clinical criteria:

- The condition must be due to hypogonadotrophic hypogonadism, **AND**
- The treatment must be following failure of 6 months' treatment with human chorionic gonadotrophin to achieve adequate spermatogenesis, **AND**
- The treatment must be administered with human chorionic gonadotrophin.

follitropin alfa 150 units (11 microgram)/0.25 mL injection, 5 x 0.25 mL injection devices

10877L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	1	..	*916.11	39.50	Bemfola [FX]

follitropin alfa 75 units (5.5 microgram)/0.125 mL injection, 5 x 0.125 mL injection devices

10865W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	1	..	*460.56	39.50	Bemfola [FX]

follitropin alfa 300 units (21.84 microgram)/0.5 mL injection, 0.5 mL cartridge

8713N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*369.45	39.50	Gonal-f Pen [SG]

follitropin alfa 450 units (32.76 microgram)/0.75 mL injection, 0.75 mL cartridge

8714P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*551.67	39.50	Gonal-f Pen [SG]

follitropin alfa 225 units (16.5 microgram)/0.375 mL injection, 5 x 0.375 mL injection devices

10876K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	1	..	*1348.44	39.50	Bemfola [FX]

follitropin alfa 900 units (65.52 microgram)/1.5 mL injection, 1.5 mL cartridge

8715Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*733.89	39.50	Gonal-f Pen [SG]

▪ **GLECAPREVIR + PIBRENTASVIR**

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 16 weeks.

glecaprevir 100 mg + pibrentasvir 40 mg film-coated tablet, 84

11344C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	18817.71	39.50	Maviret [VE]

NP

▪ **GLECAPREVIR + PIBRENTASVIR**

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 8 weeks.

glecaprevir 100 mg + pibrentasvir 40 mg film-coated tablet, 84

11353M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	18817.71	39.50	Maviret [VE]

NP

■ GLECAPREVIR + PIBRENTASVIR

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

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

glecaprevir 100 mg + pibrentasvir 40 mg film-coated tablet, 84

11354N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	18817.71	39.50	Maviret [VE]

■ GLYCOPYRRONIUM

Note The treatment must not be used in combination with a LAMA/LABA or SAMA

Note A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note A SAMA includes ipratropium

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

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

Restricted benefit

Chronic obstructive pulmonary disease (COPD)

glycopyrronium 50 microgram powder for inhalation, 30 capsules

10059K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	62.21	39.50	seebri breezhaler [NV]

■ GOLIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, golimumab, infliximab and vedolizumab for adult patients with ulcerative colitis. Patients are eligible for PBS-subsidised treatment with either adalimumab, golimumab, infliximab or vedolizumab at any one time.

Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, golimumab, infliximab and vedolizumab only.

From 1 June 2018, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial each of PBS-subsidised adalimumab, golimumab, infliximab or vedolizumab without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, golimumab infliximab or vedolizumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab, vedolizumab treatment prior to 1 June 2018 is considered to start their first cycle as of 1 June 2018. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, golimumab, infliximab or vedolizumab more than once. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to commence the next cycle.

The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, golimumab, infliximab or vedolizumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, golimumab, infliximab or vedolizumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of either adalimumab, golimumab, infliximab or vedolizumab in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

(1) How to prescribe PBS-subsidised treatment with adalimumab, golimumab, infliximab and vedolizumab after 1 June 2018.

(a) Initial treatment. Applications for initial treatment should be made where:

- an adult patient has received no prior PBS-subsidised treatment with adalimumab, golimumab, infliximab or vedolizumab in this treatment cycle and wishes to commence such therapy (Initial 1); or
- an adult patient has received prior PBS-subsidised (initial or continuing) adalimumab, golimumab, infliximab or vedolizumab therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- an adult patient wishes to re-commence treatment with adalimumab, golimumab, infliximab or vedolizumab following a break in PBS-subsidised therapy with the same agent (Initial 2).

Treatment authorisations under Initial 1 and Initial 2 will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for golimumab, infliximab and vedolizumab.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab, and this assessment must be provided to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine. For second and subsequent courses of PBS-subsidised biological medicine 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 provided to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with adalimumab, golimumab, infliximab or vedolizumab 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 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 supply of treatment. Assessments of response to a course of PBS-subsidised therapy must be provided to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not provided to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised treatment is approved, a patient may swap if eligible to the alternate adalimumab, golimumab, infliximab or vedolizumab treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy. A patient may trial an alternate treatment at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, golimumab, infliximab or vedolizumab at the time of the application. However, they cannot swap to a particular therapy if they have failed to respond to prior treatment with that drug once within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

(3) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised adalimumab, golimumab, infliximab or vedolizumab therapy of at least 5 years, must requalify for initial 1 treatment with respect to the scores of disease severity. A patient must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for induction of remission for a minimum of 3 consecutive months, and, either azathioprine or 6-mercaptopurine for a minimum of 3 consecutive months or a tapered course of oral steroids over a 6 week period followed by an appropriately dosed thiopurine agent for a minimum of 3 consecutive months (unless intolerance develops necessitating permanent treatment withdrawal to these agents). These above prior treatments must have been received immediately prior to the time the scores of disease severity being used to trial a second or subsequent course are measured.

(4) Patients 'grandfathered' onto PBS-subsidised treatment with golimumab.

A patient who commenced treatment with golimumab for moderate to severe ulcerative colitis prior to 1 June 2018 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 3 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

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

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

Population criteria:

- Patient must be aged 18 years or older.

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

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the signed patient acknowledgement.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 1 month old at the time of application. Patients who fail to achieve a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 or have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose for patients administered doses at weeks 0, 2, 6 and 10 so that there is adequate time for a response to be demonstrated.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment.

A maximum of 14 weeks of treatment with this drug will be approved under this criterion. A loading dose of 200 mg at week 0 and a dose of 100 mg at weeks 2, 6 and 10.

Patients must have signed a patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Note Details of accepted toxicities including severity can be found on the Department of Human Services website at www.humanservices.gov.au.

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

Moderate to severe ulcerative colitis

Treatment Phase: Change or Re-commencement of treatment after a break in therapy of less than 5 years (Initial 2)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with adalimumab, golimumab, infliximab or vedolizumab for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with golimumab for this condition in the current treatment cycle.

Population criteria:

- Patient must be aged 18 years or older.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of this drug within the timelines specified in the relevant restriction. If the response assessment to the previous course of this drug is not submitted as detailed in the relevant restriction, the patient will be deemed to have failed therapy with this drug.

A maximum of 14 weeks of treatment with this drug will be approved under this criterion. A loading dose of 200 mg at week 0 and a dose of 100 mg at weeks 2, 6 and 10.

Application for authorisation of change or recommencement treatment must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) Mayo clinical assessment (to demonstrate response to prior treatment).

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

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply for Initial 1 and Initial 2

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 restriction to complete 14 weeks of treatment (weeks 0, 2, 6 and 10); OR
- Patient must have received insufficient therapy with this drug under the Initial 2 restriction to complete 14 weeks of treatment (weeks 0, 2, 6 and 10).

Population criteria:

- Patient must be aged 18 years or older.

Note Authority approval for sufficient therapy to complete the balance of supply 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).

golimumab 100 mg/mL injection, 1 mL injection device

11382C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	4	..	1318.17	39.50	Simponi [JC]

▪ **IBRUTINIB**

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

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

Note Special Pricing Arrangements apply.

Authority required

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

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
 - The condition must have relapsed or be refractory to at least one prior therapy, **AND**
 - Patient must have a WHO performance status of 0 or 1, **AND**
 - Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
 - Patient must be considered unsuitable for treatment or retreatment with a purine analogue.
- A patient is considered unsuitable for treatment or retreatment with a purine analogue as demonstrated by at least one of the following:
- a) Failure to respond (stable disease or disease progression on treatment), or a progression-free interval of less than 3 years from treatment with a purine analogue-based therapy and anti-CD20-containing chemoimmunotherapy regimen after at least two cycles;
 - b) Age is 70 years or older;
 - c) Age is 65 years or older and the presence of comorbidities (Cumulative Illness Rating Scale of 6 or greater, or creatinine clearance of less than 70 mL/min) that might place the patient at an unacceptable risk for treatment-related toxicity with purine analogue-based therapy, provided they have received one or more prior treatment including at least two cycles of an alkylating agent-based (or purine analogue-based) anti-CD20 antibody-containing chemoimmunotherapy regimen;
 - d) History of purine analogue-associated autoimmune anaemia or autoimmune thrombocytopenia;
 - e) Evidence of one or more 17p chromosomal deletions demonstrated by fluorescence in situ hybridisation (FISH).

Authority required

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

Treatment Phase: Continuing treatment

Clinical criteria:

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

ibrutinib 140 mg capsule, 90

11213E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	8784.33	39.50	Imbruvica [JC]

▪ **IBRUTINIB**

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

Mantle cell lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

Authority required

Mantle cell lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

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

Authority required

Mantle cell lymphoma

Treatment Phase: Grandfather treatment

Clinical criteria:

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 August 2018, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

ibrutinib 140 mg capsule, 120

11419B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	11662.09	39.50	Imbruvica [JC]

▪ **INDACATEROL**

Note This drug is not PBS-subsidised for the treatment of asthma.

Note The treatment must not be used in combination with an ICS/LABA, or LAMA/LABA

Note A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note An ICS/LABA includes budesonide/formoterol, fluticasone/salmeterol, or fluticasone/vilanterol

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

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

Restricted benefit

Chronic obstructive pulmonary disease (COPD)

indacaterol 150 microgram powder for inhalation, 30 capsules

5134F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	59.66	39.50	Onbrez [NV]

indacaterol 300 microgram powder for inhalation, 30 capsules

5137J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	59.66	39.50	Onbrez [NV]

▪ **INDACATEROL + GLYCOPYRRONIUM**

Note This product is not PBS-subsidised for the treatment of asthma.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Note The treatment must not be used in combination with an ICS/LABA, LAMA, LABA, or SAMA

Note A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

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

Note A SAMA includes ipratropium

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

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

Authority required (STREAMLINED)

7798

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); OR
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR
- Patient must have been stabilised on a combination of a LAMA and a LABA.

indacaterol 110 microgram + glycopyrronium 50 microgram powder for inhalation, 30 capsules

10156M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	90.77	39.50	ultibro breezhaler 110/50 [NV]

▪ **INSULIN DEGLUDEC + INSULIN ASPART**

Note Special Pricing Arrangements apply.

insulin degludec 70 units/mL + insulin aspart 30 units/mL injection, 5 x 3 mL injection devices

11417X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	1	..	*372.24	39.50	Ryzodeg Flextouch [NO]

insulin degludec 70 units/mL + insulin aspart 30 units/mL injection, 5 x 3 mL cartridges

11426J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	1	..	*372.24	39.50	Ryzodeg Penfill [NO]

■ IPRATROPIUM**Restricted benefit**

Asthma

Clinical criteria:

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

Restricted benefit

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

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

ipratropium bromide 500 microgram/mL inhalation solution, 30 x 1 mL ampoules

8238N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*30.51	31.74	^a Aeron 500 [QA]	^a APO-Ipratropium [TX]
						^a Ipratrin Adult [AF]	
			^b 0.50	*31.01	31.74	^a Atrovent Adult [BY]	

ipratropium bromide 250 microgram/mL inhalation solution, 30 x 1 mL ampoules

1542E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*27.57	28.80	^a Aeron 250 [QA]	^a APO-Ipratropium [TX]
						^a Ipratrin [AF]	
			^b 0.50	*28.07	28.80	^a Atrovent [BY]	

■ MONTELUKAST

Note This drug is not PBS-subsidised for use in a patient aged 15 years or older, or for use in addition to a long-acting beta-agonist in any age group, or for use as a single second line preventer, as an alternative to corticosteroids, in a child aged 6 to 14 years with moderate to severe asthma.

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)**6674**

Asthma

Treatment Phase: First-line prevention

Clinical criteria:

- The condition must be frequent intermittent; OR
- The condition must be mild persistent, **AND**
- The treatment must be the single preventer agent, **AND**
- The treatment must be an alternative to sodium cromoglycate; OR
- The treatment must be an alternative to nedocromil sodium.

Population criteria:

- Patient must be aged 6 to 14 years inclusive.

Authority required (STREAMLINED)**7781**

Asthma

Treatment Phase: Prevention of condition

Clinical criteria:

- The condition must be exercise-induced, **AND**
- The treatment must be as an alternative to adding salmeterol xinafoate; OR
- The treatment must be an alternative to adding formoterol fumarate, **AND**
- The condition must be otherwise well controlled while receiving optimal dose inhaled corticosteroid, **AND**
- Patient must require short-acting beta-2 agonist 3 or more times per week for prevention or relief of residual exercise-related symptoms.

Population criteria:

- Patient must be aged 6 to 14 years inclusive.

montelukast 5 mg chewable tablet, 28

8628D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.06	19.29	^a APO-Montelukast [TX] ^a Chem mart Montelukast [CH] ^a Montelukast AN [EA] ^a Montelukast Sandoz 5 [SZ] ^a Terry White Chemists Montelukast [TW]	^a Auro-Montelukast Tabs 5 [DO] ^a Lukair [AL] ^a Montelukast GH [GQ] ^a Respikast 5 [RW]
			^B 3.00	21.06	19.29	^a Singulair [MK]	

■ PEGINTERFERON ALFA-2A**Note** Special Pricing Arrangements apply.**peginterferon alfa-2a 135 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

11416W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	1109.16	39.50	Pegasys [RO]

peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes

11037X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	1272.27	39.50	Pegasys [RO]

■ PERAMPANEL**Note** No applications for increased maximum quantities will be authorised.**Authority required (STREAMLINED)****7815**

Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a neurologist.

Clinical criteria:

- The condition must have failed to be controlled satisfactorily by at least two anti-epileptic drugs, **AND**
- The treatment must be in combination with at least one PBS-subsidised anti-epileptic drug, **AND**
- The treatment must be for dose titration purposes.

Population criteria:

- Patient must be aged 12 years or older.

perampanel 2 mg tablet, 7

11436X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*52.71	39.50	Fycompa [EI]

■ PERAMPANEL**Note** No applications for increased maximum quantities will be authorised.**Note** Special Pricing Arrangements apply.**Note Continuing Therapy Only:**

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

Authority required (STREAMLINED)**7789**

Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures

Treatment Phase: Continuing treatment

Clinical criteria:

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

Population criteria:

- Patient must be aged 12 years or older.

perampanel 6 mg tablet, 28

11407J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	261.96	39.50	Fycompa [EI]

perampanel 12 mg tablet, 28

11409L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	347.57	39.50	Fycompa [EI]

perampanel 10 mg tablet, 28

11428L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	347.57	39.50	Fycompa [EI]

perampanel 4 mg tablet, 28

11418Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	176.82	39.50	Fycompa [EI]

perampanel 8 mg tablet, 28

11429M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	347.57	39.50	Fycompa [EI]

■ PERICIAZINE**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.

periciazine 2.5 mg tablet, 84

11413Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	14.30	15.53	Neulactil [SW]

periciazine 10 mg tablet, 84

11427K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	17.43	18.66	Neulactil [SW]

■ PIRFENIDONE

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).

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

Idiopathic pulmonary fibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised treatment 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.

pirfenidone 801 mg tablet, 90

11410M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3066.04	39.50	Esbriet [RO]

■ PIRFENIDONE

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

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, **AND**
- The treatment must be the sole PBS-subsidised treatment 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.

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.

Patient must not have an acute respiratory infection at the time of FVC testing.

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

- a) a completed authority prescription form; and
- b) a completed IPF Authority Application Supporting Information Form; and
- c) a signed patient acknowledgement.

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: Initial treatment 2 - change or re-commencement of treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with nintedanib or pirfenidone for this condition, **AND**
- The treatment must be the sole PBS-subsidised treatment 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 Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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, **AND**
- The treatment must be the sole PBS-subsidised treatment 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).

pirfenidone 267 mg tablet, 90

11406H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*3066.03	39.50	Esbriet [RO]

■ SALBUTAMOL

Note Pharmaceutical benefits that have a 30 x 2 pack size and a 20 x 3 pack size are equivalent for the purposes of substitution.

Restricted benefit

Asthma

Clinical criteria:

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

Restricted benefit

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

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

salbutamol 2.5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules

2000G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*19.33	20.56	^a APO-Salbutamol [TX]	^a Salbutamol Actavis [EA]
						^a Salbutamol AN [ED]	^a Salbutamol Sandoz [SZ]
				^b 0.50	*19.83	20.56	^a Asmol 2.5 uni-dose [AF]

salbutamol 2.5 mg/2.5 mL inhalation solution, 20 x 2.5 mL ampoules

11130T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	^b 2.01	*21.36	20.58	^a Ventolin Nebules [GK]

salbutamol 5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules

2001H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*19.75	20.98	^a APO-Salbutamol [TX]	^a Salbutamol Actavis [EA]

NP

				^a Salbutamol AN [ED]	^a Salbutamol Sandoz [SZ]
			^B 0.50	*20.25	20.98
				^a Asmol 5 uni-dose [AF]	

NP

salbutamol 5 mg/2.5 mL inhalation solution, 20 x 2.5 mL ampoules

11095Y

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
3	5	^B 1.98	*21.75	21.00	^a Ventolin Nebules [GK]

■ TIOTROPIUM

Note The treatment must not be used in combination with a LAMA/LABA or SAMA

Note A LAMA/LABA includes acclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note A SAMA includes ipratropium

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

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

Restricted benefit

Bronchospasm and dyspnoea associated with chronic obstructive pulmonary disease

Treatment Phase: Long-term maintenance treatment

tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations

10509D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	52.65	39.50	Spiriva Respimat [BY]

■ TIOTROPIUM

Note The treatment must not be used in combination with a LAMA/LABA or SAMA

Note A LAMA/LABA includes acclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note A SAMA includes ipratropium

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

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

Restricted benefit

Chronic obstructive pulmonary disease (COPD)

tiotropium 18 microgram powder for inhalation, 30 capsules

8626B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	52.65	39.50	Spiriva [BY]

■ TIOTROPIUM + OLODATEROL

Note This product is not PBS-subsidised for the treatment of asthma.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Note The treatment must not be used in combination with an ICS/LABA, LAMA, LABA, or SAMA

Note A LAMA includes tiotropium, glycopyrronium, acclidinium or umeclidinium.

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

Note A SAMA includes ipratropium

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

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

Authority required (STREAMLINED)

7798

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); OR
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR
- Patient must have been stabilised on a combination of a LAMA and a LABA.

tiotropium 2.5 microgram/actuation + olodaterol 2.5 microgram/actuation inhalation solution, 60 actuations

10557P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	5	..	83.24	39.50	Spolto Respimat [BY]

■ UMECLIDINIUM

Note The treatment must not be used in combination with a LAMA/LABA or SAMA

Note A LAMA/LABA includes acclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note A SAMA includes ipratropium

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

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

Restricted benefit

Chronic obstructive pulmonary disease (COPD)

umeclidinium 62.5 microgram/actuation inhalation: powder for, 30 actuations

10187E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	62.21	39.50	Incruse Ellipta [GK]

▪ **UMECLIDINIUM + VILANTEROL**

Note This product is not PBS-subsidised for the treatment of asthma.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Note The treatment must not be used in combination with an ICS/LABA, LAMA, LABA, or SAMA

Note A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

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

Note A SAMA includes ipratropium

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

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

Authority required (STREAMLINED)

7798

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); OR
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR
- Patient must have been stabilised on a combination of a LAMA and a LABA.

umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations

10188F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	92.80	39.50	Anoro Ellipta 62.5/25 [GK]

Highly Specialised Drugs Program (Private Hospital)

■ BACLOFEN

Note Pharmaceutical benefits that have the forms baclofen 10 mg/5 mL intrathecal injection, 5 mL ampoule, baclofen 10 mg/5 mL intrathecal injection, 5 x 5 mL ampoules and baclofen 10 mg/5 mL intrathecal injection, 10 x 5 mL ampoules are equivalent for the purposes of substitution.

Authority required

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity of cerebral origin.

Authority required

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to multiple sclerosis.

Authority required

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord injury.

Authority required

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord disease.

baclofen 10 mg/5 mL intrathecal injection, 5 x 5 mL ampoules

11420C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	..	..	*1293.59	^a Bacthecal [DZ]

baclofen 10 mg/5 mL intrathecal injection, 10 x 5 mL ampoules

11128Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1293.59	^a Sintetica Baclofen Intrathecal [BZ]

baclofen 10 mg/5 mL intrathecal injection, 5 mL ampoule

6284R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	10	..	..	*1293.59	^a Bacthecal [DZ]	^a Lioresal Intrathecal [NV]

■ CLOZAPINE

Note Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed: Pfizer ClopineCentral.

Authority required

Schizophrenia

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a psychiatrist or in consultation with the psychiatrist affiliated with the hospital or specialised unit managing the patient.

Clinical criteria:

- Patient must be non-responsive to other neuroleptic agents; OR
 - Patient must be intolerant of other neuroleptic agents.
- Patients must complete at least 18 weeks of initial treatment under this restriction before being able to qualify for treatment under the continuing restriction.

The name of the consulting psychiatrist should be included in the patient's medical records.

A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

clozapine 50 mg/mL oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
11415T	±1	..	..	147.69	Versacloz [PF]

■ GLECAPREVIR + PIBRENTASVIR

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 16 weeks.

glecaprevir 100 mg + pibrentasvir 40 mg film-coated tablet, 84

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
11337Q	1	3	..	18713.96	Maviret [VE]

■ GLECAPREVIR + PIBRENTASVIR

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

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

glecaprevir 100 mg + pibrentasvir 40 mg film-coated tablet, 84

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
11346E	1	2	..	18713.96	Maviret [VE]

■ GLECAPREVIR + PIBRENTASVIR

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 8 weeks.

glecaprevir 100 mg + pibrentasvir 40 mg film-coated tablet, 84

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
11355P	1	1	..	18713.96	Maviret [VE]

■ INFLIXIMAB

Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term "biological medicine" appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS- subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab or infliximab without having to experience a disease flare when swapping to the alternate agent.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab or infliximab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab or infliximab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab or infliximab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab or infliximab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab or infliximab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised adalimumab or infliximab therapy after 1 April 2011.

(a) Initial treatment. Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab or infliximab therapy in this treatment cycle and wishes to commence such therapy (Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1); or

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

(iii) a patient wishes to re-commence treatment with adalimumab or infliximab following a break in PBS-subsidised therapy with that agent (Change or Re-commencement of treatment after a break in therapy of less than 5 years (Initial 2)

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

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 biological medicine.

For subsequent courses of PBS-subsidised adalimumab or infliximab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab.

One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with adalimumab or infliximab, 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 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 supply of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.

A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab or infliximab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

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

(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 submitted with the first authority application for adalimumab or infliximab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

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

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:

- (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
- (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Each application for subsequent continuing treatment with this drug must include an assessment of the patient's response to the prior course of therapy. If the response assessment is not provided at the time of application the patient will be deemed to have failed this course of treatment.

Patients are eligible to receive subsequent continuing treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.

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.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

infliximab 100 mg injection, 1 vial

11432Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	535.01	^a Inflectra [PF]	^a Renflexis [MK]

■ INFLIXIMAB

Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term "biological medicine" appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS- subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab or infliximab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab or infliximab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab or infliximab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab or infliximab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab or infliximab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab or infliximab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised adalimumab or infliximab therapy after 1 April 2011.

(a) Initial treatment. Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab or infliximab therapy in this treatment cycle and wishes to commence such therapy (Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1); or

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

(iii) a patient wishes to re-commence treatment with adalimumab or infliximab following a break in PBS-subsidised therapy with that agent (Change or Re-commencement of treatment after a break in therapy of less than 5 years (Initial 2)

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

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 biological medicine.

For subsequent courses of PBS-subsidised adalimumab or infliximab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with adalimumab or infliximab, 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 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 supply of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.

A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab or infliximab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

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

(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 submitted with the first authority application for adalimumab or infliximab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

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

Complex refractory Fistulising Crohn disease

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

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

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:

- (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
- (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The most recent fistula assessment must be no more than 1 month old at the time of application.

Each application for subsequent continuing treatment with this drug must include an assessment of the patient's response to the prior course of therapy. If the response assessment is not provided at the time of application the patient will be deemed to have failed this course of treatment.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

infliximab 100 mg injection, 1 vial

11412P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	535.01	Remicade [JC]

■ INFLIXIMAB

Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term "biological medicine" appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS- subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab or infliximab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab or infliximab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab or infliximab treatment prior to 1 April 2011 is considered to have

started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab or infliximab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab or infliximab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab or infliximab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised adalimumab or infliximab therapy after 1 April 2011.

(a) Initial treatment. Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab or infliximab therapy in this treatment cycle and wishes to commence such therapy (Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1); or

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

(iii) a patient wishes to re-commence treatment with adalimumab or infliximab following a break in PBS-subsidised therapy with that agent (Change or Re-commencement of treatment after a break in therapy of less than 5 years (Initial 2)

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

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 biological medicine.

For subsequent courses of PBS-subsidised adalimumab or infliximab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab.

One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with adalimumab or infliximab, 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 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 supply of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.

A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab or infliximab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

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

(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 submitted with the first authority application for adalimumab or infliximab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
 - Patient must have an externally draining enterocutaneous or rectovaginal fistula.
- Applications for authorisation must be made in writing and must include:

-
- (a) a completed authority prescription form; and
(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and
(ii) a signed patient acknowledgement.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services 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 to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

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

Note It is recommended that an application for the first continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the first continuing treatment criteria for PBS-subsidised treatment with this drug.

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

Complex refractory Fistulising Crohn disease

Treatment Phase: Change or Re-commencement of treatment after a break in therapy of less than 5 years (Initial 2)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

- (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and
(ii) details of prior biological medicine treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 1 month old at the time of application.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological medicine therapy within the timeframes specified in the relevant restriction.

If the response assessment to the previous course of biological medicine treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of biological medicine.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services 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 to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note It is recommended that an application for the first continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the first continuing treatment criteria for PBS-subsidised treatment with this drug.

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

Complex refractory Fistulising Crohn disease
Treatment Phase: Balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Change or Re-commencement of treatment after a break in therapy of less than 5 years (Initial 2) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 3 doses (Initial 1 or Initial 2 treatment) or 2 repeats (first Continuing or Subsequent Continuing treatment).

Note Authority approval for sufficient therapy to complete the balance of supply 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).

Authority required

Complex refractory Fistulising Crohn disease
Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

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

An adequate response is defined as:

- (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
- (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The most recent fistula assessment must be no more than 1 month old at the time of application.

The application for first continuing treatment with this drug must include an assessment of the patient's response to the initial course of treatment. The assessment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course.

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

A maximum of 24 weeks of treatment with this drug will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly.

Up to a maximum of 2 repeats will 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

infliximab 100 mg injection, 1 vial

9674E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	535.01	^a Inflectra [PF] ^a Renflexis [MK]	^a Remicade [JC]

■ LENALIDOMIDE

Note Special Pricing Arrangements apply.

Authority required

Multiple myeloma

Treatment Phase: Initial PBS-subsidised treatment

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant, **AND**
- Patient must not be receiving concomitant PBS-subsidised bortezomib, carfilzomib or thalidomide or its analogues. Progressive disease is defined as at least 1 of the following:
 - (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
 - (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
 - (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
 - (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
 - (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
 - (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
 - (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

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

- (1) a completed authority prescription form; and
- (2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; details of the basis of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response; and
- (3) a signed patient acknowledgment.

To enable confirmation of eligibility for treatment, current diagnostic reports of at least one of the following must be provided:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

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

Multiple myeloma

Treatment Phase: Continuing PBS-subsidised treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for relapsed or refractory multiple myeloma, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with dexamethasone, **AND**
- Patient must not be receiving concomitant PBS-subsidised bortezomib, carfilzomib or thalidomide or its analogues. Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

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).

Note Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

lenalidomide 25 mg capsule, 21

9645P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	6634.78	Revlimid [CJ]

lenalidomide 10 mg capsule, 21

9643M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5408.45	Revlimid [CJ]

lenalidomide 5 mg capsule, 21

9642L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5170.05	Revlimid [CJ]

lenalidomide 15 mg capsule, 21

9644N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	6299.82	Revlimid [CJ]

▪ PEGFILGRASTIM

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; OR
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe

6363X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	1222.29	^a Neulasta [AN]	^a Ristempa [GV]

▪ POMALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

Note Special Pricing Arrangements apply.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be in combination with dexamethasone, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant, **AND**
- Patient must have experienced treatment failure with lenalidomide, **AND**
- Patient must have experienced treatment failure with bortezomib, **AND**
- Patient must not be receiving concomitant PBS-subsidised bortezomib, carfilzomib or thalidomide or its analogues. Bortezomib treatment failure is the absence of achieving at least a partial response or as progressive disease during treatment or within 6 months of discontinuing treatment with bortezomib. Lenalidomide treatment failure is progressive disease during treatment or within 6 months of discontinuing treatment with lenalidomide. Progressive disease is defined as at least 1 of the following:
(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

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

- (1) a completed authority prescription form; and
- (2) a completed Multiple Myeloma pomalidomide Authority Application Supporting Information form; and
- (3) reports demonstrating the patient has failed treatment with lenalidomide and bortezomib.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

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
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug, **AND**
 - Patient must not have progressive disease, **AND**
 - The treatment must be in combination with dexamethasone, **AND**
 - Patient must not be receiving concomitant PBS-subsidised bortezomib, carfilzomib or thalidomide or its analogues.
- Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

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).

Note Written applications for authority to prescribe should be forwarded to:

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

pomalidomide 3 mg capsule, 21

10417G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	10547.29	Pomalyst [CJ]

pomalidomide 4 mg capsule, 21

10386P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	10547.29	Pomalyst [CJ]

Highly Specialised Drugs Program (Public Hospital)

■ BACLOFEN

Note Pharmaceutical benefits that have the forms baclofen 10 mg/5 mL intrathecal injection, 5 mL ampoule, baclofen 10 mg/5 mL intrathecal injection, 5 x 5 mL ampoules and baclofen 10 mg/5 mL intrathecal injection, 10 x 5 mL ampoules are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

6925

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity of cerebral origin.

Authority required (STREAMLINED)

6939

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to multiple sclerosis.

Authority required (STREAMLINED)

6940

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord injury.

Authority required (STREAMLINED)

6911

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord disease.

baclofen 10 mg/5 mL intrathecal injection, 5 x 5 mL ampoules

11421D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	..	..	*1246.30	^a Bacthecal [DZ]

baclofen 10 mg/5 mL intrathecal injection, 10 x 5 mL ampoules

11126N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1246.30	^a Sintetica Baclofen Intrathecal [BZ]

baclofen 10 mg/5 mL intrathecal injection, 5 mL ampoule

5617P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	10	..	..	*1246.30	^a Bacthecal [DZ]	^a Lioresal Intrathecal [NV]

■ CLOZAPINE

Note Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed: Pfizer ClopineCentral.

Authority required (STREAMLINED)

5015

Schizophrenia

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a psychiatrist or in consultation with the psychiatrist affiliated with the hospital or specialised unit managing the patient.

Clinical criteria:

- Patient must be non-responsive to other neuroleptic agents; OR
- Patient must be intolerant of other neuroleptic agents.

Patients must complete at least 18 weeks of initial treatment under this restriction before being able to qualify for treatment under the continuing restriction.

The name of the consulting psychiatrist should be included in the patient's medical records.

A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

clozapine 50 mg/mL oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
11433R	±1	..	..	135.00	Versacloz [PF]

■ GLECAPREVIR + PIBRENTASVIR

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 8 weeks.

glecaprevir 100 mg + pibrentasvir 40 mg film-coated tablet, 84

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
11332K	1	1	..	18666.67	Maviret [VE]

■ GLECAPREVIR + PIBRENTASVIR

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 16 weeks.

glecaprevir 100 mg + pibrentasvir 40 mg film-coated tablet, 84

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
11333L	1	3	..	18666.67	Maviret [VE]

■ GLECAPREVIR + PIBRENTASVIR

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

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

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

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

glecaprevir 100 mg + pibrentasvir 40 mg film-coated tablet, 84

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
11345D	1	2	..	18666.67	Maviret [VE]

■ INFLIXIMAB

Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term "biological medicine" appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS- subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab or infliximab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab or infliximab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab or infliximab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab or infliximab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab or infliximab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab or infliximab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised adalimumab or infliximab therapy after 1 April 2011.

(a) Initial treatment. Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab or infliximab therapy in this treatment cycle and wishes to commence such therapy (Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1); or

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

(iii) a patient wishes to re-commence treatment with adalimumab or infliximab following a break in PBS-subsidised therapy with that agent (Change or Re-commencement of treatment after a break in therapy of less than 5 years (Initial 2)

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

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 biological medicine.

For subsequent courses of PBS-subsidised adalimumab or infliximab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab.

One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with adalimumab or infliximab, 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 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 supply of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.

A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab or infliximab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

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

(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 submitted with the first authority application for adalimumab or infliximab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

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

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

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

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:

- (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
- (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The most recent fistula assessment must be no more than 1 month old at the time of application.

Each application for subsequent continuing treatment with this drug must include an assessment of the patient's response to the prior course of therapy. If the response assessment is not provided at the time of application the patient will be deemed to have failed this course of treatment.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

infliximab 100 mg injection, 1 vial

11424G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	507.42	Remicade [JC]

■ INFLIXIMAB

Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term "biological medicine" appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab or infliximab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab or infliximab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab or infliximab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab or infliximab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab or infliximab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab or infliximab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised adalimumab or infliximab therapy after 1 April 2011.

(a) Initial treatment. Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab or infliximab therapy in this treatment cycle and wishes to commence such therapy (Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1); or

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

(iii) a patient wishes to re-commence treatment with adalimumab or infliximab following a break in PBS-subsidised therapy with that agent (Change or Re-commencement of treatment after a break in therapy of less than 5 years (Initial 2)

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a

minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

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 biological medicine.

For subsequent courses of PBS-subsidised adalimumab or infliximab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with adalimumab or infliximab, 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 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 supply of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.

A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab or infliximab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

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

(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 submitted with the first authority application for adalimumab or infliximab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

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

Authority required (STREAMLINED)

7847

Complex refractory Fistulising Crohn disease

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:

- (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
- (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

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

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.

Patients are eligible to receive subsequent continuing treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.

infliximab 100 mg injection, 1 vial

11423F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	2	..	*2029.68	^a Inflectra [PF]	^a Renflexis [MK]

■ INFLIXIMAB

Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term "biological medicine" appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS- subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab or infliximab without having to experience a disease flare when swapping to the alternate agent.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab or infliximab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab or infliximab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab or infliximab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab or infliximab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab or infliximab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised adalimumab or infliximab therapy after 1 April 2011.

(a) Initial treatment. Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab or infliximab therapy in this treatment cycle and wishes to commence such therapy (Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1); or

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

(iii) a patient wishes to re-commence treatment with adalimumab or infliximab following a break in PBS-subsidised therapy with that agent (Change or Re-commencement of treatment after a break in therapy of less than 5 years (Initial 2)

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

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 biological medicine.

For subsequent courses of PBS-subsidised adalimumab or infliximab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with adalimumab or infliximab, 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 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 supply of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.

A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab or infliximab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

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

(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 submitted with the first authority application for adalimumab or infliximab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have an externally draining enterocutaneous or rectovaginal fistula.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and

(ii) a signed patient acknowledgement.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services 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 to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

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

Note It is recommended that an application for the first continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the first continuing treatment criteria for PBS-subsidised treatment with this drug.

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

Complex refractory Fistulising Crohn disease

Treatment Phase: Change or Re-commencement of treatment after a break in therapy of less than 5 years (Initial 2)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and

(ii) details of prior biological medicine treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 1 month old at the time of application.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological medicine therapy within the timeframes specified in the relevant restriction.

If the response assessment to the previous course of biological medicine treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of biological medicine.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services 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 to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note It is recommended that an application for the first continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the first continuing treatment criteria for PBS-subsidised treatment with this drug.

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

Complex refractory Fistulising Crohn disease

Treatment Phase: Balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Change or Re-commencement of treatment after a break in therapy of less than 5 years (Initial 2) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 3 doses (Initial 1 or Initial 2 treatment) or 2 repeats (first Continuing or Subsequent Continuing treatment).

Note Authority approval for sufficient therapy to complete the balance of supply 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).

Authority required

Complex refractory Fistulising Crohn disease

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

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

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The most recent fistula assessment must be no more than 1 month old at the time of application.

The application for first continuing treatment with this drug must include an assessment of the patient's response to the initial course of treatment. The assessment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course.

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

A maximum of 24 weeks of treatment with this drug will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly.

Up to a maximum of 2 repeats will 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

infliximab 100 mg injection, 1 vial

9654D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	507.42	^a Inflectra [PF] ^a Renflexis [MK]	^a Remicade [JC]

▪ **LENALIDOMIDE**

Note Special Pricing Arrangements apply.

Authority required

Multiple myeloma

Treatment Phase: Initial PBS-subsidised treatment

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant, **AND**
- Patient must not be receiving concomitant PBS-subsidised bortezomib, carfilzomib or thalidomide or its analogues. Progressive disease is defined as at least 1 of the following:
 - (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
 - (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
 - (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
 - (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
 - (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
 - (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
 - (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

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

- (1) a completed authority prescription form; and
- (2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; details of the basis of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response; and
- (3) a signed patient acknowledgment.

To enable confirmation of eligibility for treatment, current diagnostic reports of at least one of the following must be provided:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

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

Multiple myeloma
Treatment Phase: Continuing PBS-subsidised treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for relapsed or refractory multiple myeloma, **AND**
 - The treatment must be as monotherapy; OR
 - The treatment must be in combination with dexamethasone, **AND**
 - Patient must not be receiving concomitant PBS-subsidised bortezomib, carfilzomib or thalidomide or its analogues.
- Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

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).

Note Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

lenalidomide 25 mg capsule, 21

5786M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	6587.49	Revlimid [CJ]

lenalidomide 10 mg capsule, 21

5784K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5361.16	Revlimid [CJ]

lenalidomide 5 mg capsule, 21

5783J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5122.76	Revlimid [CJ]

lenalidomide 15 mg capsule, 21

5785L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	6252.53	Revlimid [CJ]

■ **NUSINERSEN**

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

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

Note Special Pricing Arrangements apply.

Note 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

Spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment - Loading doses

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA.

Clinical criteria:

- The condition must 5q homozygous deletion, mutation of, or compound heterozygous mutation in the SMN1 gene of type I, II or IIIa, **AND**
- Patient must have experienced at least two of the defined signs and symptoms of SMA type I, II or IIIa prior to 3 years of age, **AND**
- The treatment must be given concomitantly with standard of care for this condition, **AND**
- The treatment must not exceed four loading doses (at days 0, 14, 28 and 63) under this restriction.

Population criteria:

- Patient must be 18 years of age or under.

Defined signs and symptoms of type I SMA are:

- i) Onset before 6 months of age; and
- ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or
- iii) Proximal weakness; or
- iv) Hypotonia; or

- v) Absence of deep tendon reflexes; or
- vi) Failure to gain weight appropriate for age; or
- vii) Any active chronic neurogenic changes; or
- viii) A compound muscle action potential below normative values for an age-matched child.

Defined signs and symptoms of type II SMA are:

- i) Onset between 6 and 18 months; and
- ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or
- iii) Proximal weakness; or
- iv) Weakness in trunk righting/derotation; or
- v) Hypotonia; or
- vi) Absence of deep tendon reflexes; or
- vii) Failure to gain weight appropriate for age; or
- viii) Any active chronic neurogenic changes; or
- ix) A compound muscle action potential below normative values for an age-matched child.

Defined signs and symptoms of type IIIa SMA are:

- i) Onset between 18 months and 3 years of age; and
- ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or
- iii) Proximal weakness; or
- iv) Hypotonia; or
- v) Absence of deep tendon reflexes; or
- vi) Failure to gain weight appropriate for age; or
- vii) Any active chronic neurogenic changes; or
- viii) A compound muscle action potential below normative values for an age-matched child.

Recognised hospitals in the management of SMA are Lady Cilento Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

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

- (a) a completed authority prescription form; and
- (b) a completed Spinal muscular atrophy PBS Authority Application - Supporting Information Form which includes the following:

- i) specification of SMA type (I, II or IIIa); and
- (ii) sign(s) and symptom(s) that the patient has experienced; and
- (iii) patient's age at the onset of sign(s) and symptom(s).

nusinersen 12 mg/5 mL injection, 5 mL vial

11363C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	110000.00	Spinraza [BD]

■ NUSINERSEN

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

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

Note Special Pricing Arrangements apply.

Note 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

Spinal muscular atrophy (SMA)

Treatment Phase: Continuing treatment - Maintenance

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given concomitantly with standard of care for this condition, **AND**
- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.

Recognised hospitals in the management of SMA are Lady Cilento Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

nusinersen 12 mg/5 mL injection, 5 mL vial

11378W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	110000.00	Spinraza [BD]

■ NUSINERSEN

Note Special Pricing Arrangements apply.

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

Note A maximum number of repeats of up to 2 may be authorised for patients requiring loading doses for days 14, 28 and 63.

Note A maximum number of repeats of up to 1 may be authorised for patients requiring loading doses for days 28 and 63.

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

Spinal muscular atrophy (SMA)

Treatment Phase: Grandfather patients

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA.

Clinical criteria:

- Patient must have previously received non-PBS-subsidised treatment for this condition with this drug prior to 1 June 2018, **AND**
- The condition must 5q homozygous deletion, mutation of, or compound heterozygous mutation in the SMN1 gene of type I, II or IIIa, **AND**
- Patient must have had experienced at least two of the defined signs and symptoms of SMA type I, II or IIIa prior to 3 years of age, **AND**
- Patient must have previously received at least one of the four loading doses at days 0, 14, 28 and 63, **AND**
- The treatment must be given concomitantly with standard of care for this condition, **AND**
- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.

Population criteria:

- Patient must have been 18 years of age or under at the time treatment with this drug was initiated for this condition; OR
- Patient must have previously received treatment with this drug for this condition under the care of clinicians with the authorised prescriber number of AP17/83146.

Defined signs and symptoms of type I SMA are:

- i) Onset before 6 months of age; and
- ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or
- iii) Proximal weakness; or
- iv) Hypotonia; or
- v) Absence of deep tendon reflexes; or
- vi) Failure to gain weight appropriate for age; or
- vii) Any active chronic neurogenic changes; or
- viii) A compound muscle action potential below normative values for an age-matched child.

Defined signs and symptoms of type II SMA are:

- i) Onset between 6 and 18 months; and
- ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or
- iii) Proximal weakness; or
- iv) Weakness in trunk righting/derotation; or
- v) Hypotonia; or
- vi) Absence of deep tendon reflexes; or
- vii) Failure to gain weight appropriate for age; or
- viii) Any active chronic neurogenic changes; or
- ix) A compound muscle action potential below normative values for an age-matched child.

Defined signs and symptoms of type IIIa SMA are:

- i) Onset between 18 months and 3 years of age; and
- ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or
- iii) Proximal weakness; or
- iv) Hypotonia; or
- v) Absence of deep tendon reflexes; or
- vi) Failure to gain weight appropriate for age; or
- vii) Any active chronic neurogenic changes; or
- viii) A compound muscle action potential below normative values for an age-matched child.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

Recognised hospitals in the management of SMA are Lady Cilento Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

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

- (a) a completed authority prescription form(s); and
- (b) a completed Spinal muscular atrophy PBS Authority Application for Grandfather patients - Supporting Information Form which includes the following:
 - (i) specification of SMA type (I, II or IIIa); and
 - (ii) sign(s) and symptom(s) that the patient has experienced; and
 - (iii) patient's age at the onset of sign(s) and symptom(s); and
 - (iv) if relevant, a copy of a TGA-approval letter to clinician with the authorised prescriber number of AP17/83146.

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.

nusinersen 12 mg/5 mL injection, 5 mL vial

11370K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	110000.00	Spinraza [BD]

▪ PEGFILGRASTIM

Authority required (STREAMLINED)

7822

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; OR
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

Authority required (STREAMLINED)

7843

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe

9514R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	1175.00	^a Neulasta [AN]	^a Ristempa [GV]

▪ POMALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

Note Special Pricing Arrangements apply.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be in combination with dexamethasone, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant, **AND**
- Patient must have experienced treatment failure with lenalidomide, **AND**
- Patient must have experienced treatment failure with bortezomib, **AND**
- Patient must not be receiving concomitant PBS-subsidised bortezomib, carfilzomib or thalidomide or its analogues. Bortezomib treatment failure is the absence of achieving at least a partial response or as progressive disease during treatment or within 6 months of discontinuing treatment with bortezomib. Lenalidomide treatment failure is progressive disease during treatment or within 6 months of discontinuing treatment with lenalidomide. Progressive disease is defined as at least 1 of the following:
 - (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
 - (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
 - (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
 - (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
 - (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
 - (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Multiple Myeloma pomalidomide Authority Application Supporting Information form; and
- (3) reports demonstrating the patient has failed treatment with lenalidomide and bortezomib.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

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
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must not have progressive disease, **AND**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must not be receiving concomitant PBS-subsidised bortezomib, carfilzomib or thalidomide or its analogues. Progressive disease is defined as at least 1 of the following:
 - (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
 - (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
 - (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
 - (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
 - (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
 - (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
 - (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

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).

Note Written applications for authority to prescribe should be forwarded to:

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

pomalidomide 3 mg capsule, 21

10406Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	10500.00	Pomalyst [CJ]

pomalidomide 4 mg capsule, 21

10387Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	10500.00	Pomalyst [CJ]

Highly Specialised Drugs Program (Community Access)

■ CLOZAPINE

Note Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed: Pfizer ClopineCentral.

Authority required (STREAMLINED)

4998

Schizophrenia

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a psychiatrist; OR
- Must be treated by an authorised medical practitioner, with the agreement of the treating psychiatrist.

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy with this drug for this condition, **AND**
 - Patient must have completed at least 18 weeks therapy, **AND**
 - Patient must be on a clozapine dosage considered stable by a treating psychiatrist, **AND**
 - The treatment must be under the supervision and direction of a psychiatrist reviewing the patient at regular intervals.
- A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

clozapine 50 mg/mL oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11422E	±1	..	..	147.69	39.50	Versacloz [PF]

IVF Treatment Program

■ FOLLITROPIN ALFA

Note Biosimilar prescribing policy Prescribing of the biosimilar brand, Bemfola, is encouraged for treatment naive patients. Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Authority required (STREAMLINED)

5027

Assisted Reproductive Technology

Clinical criteria:

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

follitropin alfa 150 units (11 microgram)/0.25 mL injection, 5 x 0.25 mL injection devices

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10873G	3	..	..	*858.75	39.50	Bemfola [FX]

follitropin alfa 75 units (5.5 microgram)/0.125 mL injection, 5 x 0.125 mL injection devices

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10861P	3	..	..	*433.02	39.50	Bemfola [FX]

follitropin alfa 300 units (21.84 microgram)/0.5 mL injection, 0.5 mL cartridge

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
6431L	2	..	..	*234.35	39.50	Gonal-f Pen [SG]

follitropin alfa 450 units (32.76 microgram)/0.75 mL injection, 0.75 mL cartridge

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
6432M	2	..	..	*347.87	39.50	Gonal-f Pen [SG]

follitropin alfa 225 units (16.5 microgram)/0.375 mL injection, 5 x 0.375 mL injection devices

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10872F	3	..	..	*1275.33	39.50	Bemfola [FX]

follitropin alfa 450 units (33 microgram)/0.75 mL injection, 5 x 0.75 mL injection devices

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10867Y	3	..	..	*2503.38	39.50	Bemfola [FX]

follitropin alfa 900 units (65.52 microgram)/1.5 mL injection, 1.5 mL cartridge

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
6433N	5	..	..	*1684.69	39.50	Gonal-f Pen [SG]

follitropin alfa 300 units (22 microgram)/0.5 mL injection, 5 x 0.5 mL injection devices

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10866X	3	..	..	*1684.68	39.50	Bemfola [FX]

■ FOLLITROPIN DELTA

Authority required (STREAMLINED)

5027

Assisted Reproductive Technology

Clinical criteria:

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

follitropin delta 36 microgram/1.08 mL injection, 1.08 mL injection device

11431P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	..	..	*1373.99	39.50	Rekovelle [FP]

follitropin delta 12 microgram/0.36 mL injection, 0.36 mL injection device

11430N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	..	..	*467.24	39.50	Rekovelle [FP]

follitropin delta 72 microgram/2.16 mL injection, 2.16 mL injection device

11414R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*2170.05	39.50	Rekovelle [FP]