



**Australian Government**

**Department of Health**



# Schedule of Pharmaceutical Benefits

*Summary of Changes*

**Effective 1 September 2018**



---

# Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 September 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 September 2018. The Schedule is updated on the first day of each month and is available on the internet at [www.pbs.gov.au](http://www.pbs.gov.au).

## Prescriber Bag Advance Notices

1 December 2018

### Deletion – Brand

10016E *Benztropine Omega, FK* – **BENZATROPINE**, benztropine mesilate 2 mg/2 mL injection, 10 x 2 mL vials

## General Pharmaceutical Benefits

### Additions

#### Addition – Item

11437Y **BARICITINIB**, baricitinib 2 mg tablet, 28 (*Olumiant*)  
11442F **BARICITINIB**, baricitinib 2 mg tablet, 28 (*Olumiant*)  
11443G **BARICITINIB**, baricitinib 4 mg tablet, 28 (*Olumiant*)  
11447L **BARICITINIB**, baricitinib 4 mg tablet, 28 (*Olumiant*)  
11452R **GUANFACINE**, guanfacine 1 mg modified release tablet, 28 (*Intuniv*)  
11451Q **GUANFACINE**, guanfacine 2 mg modified release tablet, 28 (*Intuniv*)  
11440D **GUANFACINE**, guanfacine 3 mg modified release tablet, 28 (*Intuniv*)  
11441E **GUANFACINE**, guanfacine 4 mg modified release tablet, 28 (*Intuniv*)  
11438B **LONG CHAIN TRIGLYCERIDES**, long chain triglycerides oral liquid, 15 x 225 mL bottles (*Carb zero*)  
11444H **MEDIUM CHAIN TRIGLYCERIDES**, medium chain triglycerides oral liquid, 15 x 225 mL bottles (*Betaquik*)  
11439C **PERFLUOROHEXYLOCTANE**, perfluorohexyloctane 100% eye drops, 3 mL (*Novatears*)  
11446K **PERFLUOROHEXYLOCTANE**, perfluorohexyloctane 100% eye drops, 3 mL (*Novatears*)  
11454W **PONATINIB**, ponatinib 15 mg tablet, 60 (*Iclusig*)  
11453T **PONATINIB**, ponatinib 45 mg tablet, 30 (*Iclusig*)

#### Addition – Brand

9049G *APO-Amlodipine/Atorvastatin 5/10, TX* – **AMLODIPINE + ATORVASTATIN**, amlodipine 5 mg + atorvastatin 10 mg tablet, 30  
9050H *APO-Amlodipine/Atorvastatin 5/20, TX* – **AMLODIPINE + ATORVASTATIN**, amlodipine 5 mg + atorvastatin 20 mg tablet, 30  
9051J *APO-Amlodipine/Atorvastatin 5/40, TX* – **AMLODIPINE + ATORVASTATIN**, amlodipine 5 mg + atorvastatin 40 mg tablet, 30  
9052K *APO-Amlodipine/Atorvastatin 5/80, TX* – **AMLODIPINE + ATORVASTATIN**, amlodipine 5 mg + atorvastatin 80 mg tablet, 30  
9053L *APO-Amlodipine/Atorvastatin 10/10, TX* – **AMLODIPINE + ATORVASTATIN**, amlodipine 10 mg + atorvastatin 10 mg tablet, 30

9054M	<i>APO-Amlodipine/Atorvastatin 10/20, TX</i> – <b>AMLODIPINE + ATORVASTATIN</b> , amlodipine 10 mg + atorvastatin 20 mg tablet, 30
9055N	<i>APO-Amlodipine/Atorvastatin 10/40, TX</i> – <b>AMLODIPINE + ATORVASTATIN</b> , amlodipine 10 mg + atorvastatin 40 mg tablet, 30
9056P	<i>APO-Amlodipine/Atorvastatin 10/80, TX</i> – <b>AMLODIPINE + ATORVASTATIN</b> , amlodipine 10 mg + atorvastatin 80 mg tablet, 30
1214X	<i>Aspen Pharma Pty Ltd, FM</i> – <b>CODEINE</b> , codeine phosphate hemihydrate 30 mg tablet, 20
5063L	<i>Aspen Pharma Pty Ltd, FM</i> – <b>CODEINE</b> , codeine phosphate hemihydrate 30 mg tablet, 20
2449X	<i>APO-Gliclazide, TX</i> – <b>GLICLAZIDE</b> , gliclazide 80 mg tablet, 100
8450R	<i>Glimepiride APOTEX, GX</i> – <b>GLIMEPIRIDE</b> , glimepiride 1 mg tablet, 30
8451T	<i>Glimepiride APOTEX, GX</i> – <b>GLIMEPIRIDE</b> , glimepiride 2 mg tablet, 30
8533D	<i>Glimepiride APOTEX, GX</i> – <b>GLIMEPIRIDE</b> , glimepiride 3 mg tablet, 30
8452W	<i>Glimepiride APOTEX, GX</i> – <b>GLIMEPIRIDE</b> , glimepiride 4 mg tablet, 30
3384D	<i>PRYZEX ODT, RW</i> – <b>OLANZAPINE</b> , olanzapine 15 mg orally disintegrating tablet, 28
3385E	<i>PRYZEX ODT, RW</i> – <b>OLANZAPINE</b> , olanzapine 20 mg orally disintegrating tablet, 28
8646C	<i>Tacrograf, RW</i> – <b>TACROLIMUS</b> , tacrolimus 500 microgram capsule, 100
8647D	<i>Tacrograf, RW</i> – <b>TACROLIMUS</b> , tacrolimus 1 mg capsule, 100
8648E	<i>Tacrograf, RW</i> – <b>TACROLIMUS</b> , tacrolimus 5 mg capsule, 50
5442K	<i>TOBRAMYCIN WOCKHARDT, WC</i> – <b>TOBRAMYCIN</b> , tobramycin 300 mg/5 mL inhalation solution, 56 x 5 mL ampoules

#### **Addition – Note**

1471K	<b>FLUCONAZOLE</b> , fluconazole 50 mg capsule, 28 ( <i>Diflucan, Dizole 50, Fluconazole Sandoz, Ozole</i> )
1472L	<b>FLUCONAZOLE</b> , fluconazole 100 mg capsule, 28 ( <i>Diflucan, Dizole 100, Fluconazole Sandoz, Ozole</i> )
1475P	<b>FLUCONAZOLE</b> , fluconazole 200 mg capsule, 28 ( <i>APO-Fluconazole, Diflucan, Dizole 200, Fluconazole APOTEX, Fluconazole Sandoz, Fluzole 200, Ozole</i> )
5446P	<b>FLUCONAZOLE</b> , fluconazole 50 mg/5 mL powder for oral liquid, 35 mL ( <i>Diflucan</i> )
10732W	<b>ITRACONAZOLE</b> , itraconazole 50 mg capsule, 60 ( <i>Lozanoc</i> )
8196J	<b>ITRACONAZOLE</b> , itraconazole 100 mg capsule, 60 ( <i>APO-Itraconazole, ITRANOX, Itracap, Sporanox</i> )

#### **Deletions**

##### **Deletion – Item**

11390L	<b>ADRENALINE (EPINEPHRINE)</b> , adrenaline (epinephrine) 150 microgram/0.15 mL injection, 1 dose ( <i>Emerade</i> )
11398X	<b>ADRENALINE (EPINEPHRINE)</b> , adrenaline (epinephrine) 300 microgram/0.3 mL injection, 1 dose ( <i>Emerade</i> )
2130D	<b>ALPRAZOLAM</b> , alprazolam 250 microgram tablet, 50 ( <i>Kalma 0.25</i> )
2131E	<b>ALPRAZOLAM</b> , alprazolam 500 microgram tablet, 50 ( <i>Kalma 0.5</i> )
2132F	<b>ALPRAZOLAM</b> , alprazolam 1 mg tablet, 50 ( <i>Kalma 1</i> )
10037G	<b>LONG CHAIN TRIGLYCERIDES</b> , long chain triglycerides oral liquid, 18 x 250 mL cartons ( <i>carbzero</i> )
10049X	<b>MEDIUM CHAIN TRIGLYCERIDES</b> , medium chain triglycerides oral liquid, 18 x 250 mL cartons ( <i>betaquik</i> )

##### **Deletion – Brand**

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

---

	alendronate 70 mg + colecalciferol 140 microgram (5600 units) tablet, 4
2600W	<i>Chem mart Allopurinol, CH – ALLOPURINOL,</i> allopurinol 100 mg tablet, 200
2600W	<i>Terry White Chemists Allopurinol, TW – ALLOPURINOL,</i> allopurinol 100 mg tablet, 200
2604C	<i>Chem mart Allopurinol, CH – ALLOPURINOL,</i> allopurinol 300 mg tablet, 60
2604C	<i>Terry White Chemists Allopurinol, TW – ALLOPURINOL,</i> allopurinol 300 mg tablet, 60
9049G	<i>Blooms the Chemist Amlodipine/Atorvastatin 5/10, IB – AMLODIPINE + ATORVASTATIN,</i> amlodipine 5 mg + atorvastatin 10 mg tablet, 30
9050H	<i>Blooms the Chemist Amlodipine/Atorvastatin 5/20, IB – AMLODIPINE + ATORVASTATIN,</i> amlodipine 5 mg + atorvastatin 20 mg tablet, 30
9051J	<i>Blooms the Chemist Amlodipine/Atorvastatin 5/40, IB – AMLODIPINE + ATORVASTATIN,</i> amlodipine 5 mg + atorvastatin 40 mg tablet, 30
9052K	<i>Blooms the Chemist Amlodipine/Atorvastatin 5/80, IB – AMLODIPINE + ATORVASTATIN,</i> amlodipine 5 mg + atorvastatin 80 mg tablet, 30
9053L	<i>Blooms the Chemist Amlodipine/Atorvastatin 10/10, IB – AMLODIPINE + ATORVASTATIN,</i> amlodipine 10 mg + atorvastatin 10 mg tablet, 30
9054M	<i>Blooms the Chemist Amlodipine/Atorvastatin 10/20, IB – AMLODIPINE + ATORVASTATIN,</i> amlodipine 10 mg + atorvastatin 20 mg tablet, 30
9055N	<i>Blooms the Chemist Amlodipine/Atorvastatin 10/40, IB – AMLODIPINE + ATORVASTATIN,</i> amlodipine 10 mg + atorvastatin 40 mg tablet, 30
9056P	<i>Blooms the Chemist Amlodipine/Atorvastatin 10/80, IB – AMLODIPINE + ATORVASTATIN,</i> amlodipine 10 mg + atorvastatin 80 mg tablet, 30
8213G	<i>Atorvastatin SCP 10, RZ – ATORVASTATIN,</i> atorvastatin 10 mg tablet, 30
9230T	<i>Atorvastatin SCP 10, RZ – ATORVASTATIN,</i> atorvastatin 10 mg tablet, 30
8214H	<i>Atorvastatin SCP 20, RZ – ATORVASTATIN,</i> atorvastatin 20 mg tablet, 30
9231W	<i>Atorvastatin SCP 20, RZ – ATORVASTATIN,</i> atorvastatin 20 mg tablet, 30
8215J	<i>Atorvastatin SCP 40, RZ – ATORVASTATIN,</i> atorvastatin 40 mg tablet, 30
9232X	<i>Atorvastatin SCP 40, RZ – ATORVASTATIN,</i> atorvastatin 40 mg tablet, 30
8521L	<i>Atorvastatin SCP 80, RZ – ATORVASTATIN,</i> atorvastatin 80 mg tablet, 30
9233Y	<i>Atorvastatin SCP 80, RZ – ATORVASTATIN,</i> atorvastatin 80 mg tablet, 30
8255L	<i>Chem mart Carvedilol 3.125 mg, CH – CARVEDILOL,</i> carvedilol 3.125 mg tablet, 30
8255L	<i>Terry White Chemists Carvedilol 3.125 mg, TW – CARVEDILOL,</i> carvedilol 3.125 mg tablet, 30
8256M	<i>Chem mart Carvedilol 6.25 mg, CH – CARVEDILOL,</i> carvedilol 6.25 mg tablet, 60
8256M	<i>Terry White Chemists Carvedilol 6.25 mg, TW – CARVEDILOL,</i> carvedilol 6.25 mg tablet, 60
8257N	<i>Chem mart Carvedilol 12.5 mg, CH – CARVEDILOL,</i> carvedilol 12.5 mg tablet, 60
8257N	<i>Terry White Chemists Carvedilol 12.5 mg, TW – CARVEDILOL,</i> carvedilol 12.5 mg tablet, 60
8258P	<i>Chem mart Carvedilol 25 mg, CH – CARVEDILOL,</i> carvedilol 25 mg tablet, 60
8258P	<i>Terry White Chemists Carvedilol 25 mg, TW – CARVEDILOL,</i> carvedilol 25 mg tablet, 60
1214X	<i>Fawns and McAllan Proprietary Limited, FM – CODEINE,</i> codeine phosphate hemihydrate 30 mg tablet, 20
5063L	<i>Fawns and McAllan Proprietary Limited, FM – CODEINE,</i> codeine phosphate hemihydrate 30 mg tablet, 20
9106G	<i>Chem mart Doxycycline, CH – DOXYCYCLINE,</i> doxycycline 50 mg tablet, 25
9106G	<i>Terry White Chemists Doxycycline, TW – DOXYCYCLINE,</i> doxycycline 50 mg tablet, 25
10781K	<i>Chem mart Doxycycline, CH – DOXYCYCLINE,</i> doxycycline 100 mg tablet, 7
10781K	<i>Terry White Chemists Doxycycline, TW – DOXYCYCLINE,</i> doxycycline 100 mg tablet, 7
5082L	<i>Chem mart Doxycycline, CH – DOXYCYCLINE,</i> doxycycline 100 mg tablet, 7
5082L	<i>Terry White Chemists Doxycycline, TW – DOXYCYCLINE,</i> doxycycline 100 mg tablet, 7
9105F	<i>Chem mart Doxycycline, CH – DOXYCYCLINE,</i> doxycycline 100 mg tablet, 7
9105F	<i>Terry White Chemists Doxycycline, TW – DOXYCYCLINE,</i> doxycycline 100 mg tablet, 7

---

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

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

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

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

11408K *APO-Ezetimibe, TX – EZETIMIBE*, ezetimibe 10 mg tablet, 30

11408K *Blooms The Chemist Ezetimibe, IB – EZETIMIBE*, ezetimibe 10 mg tablet, 30

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

2449X *Terry White Chemists Gliclazide, 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 *Terry White Chemists Lisinopril, TW – LISINOPRIL*, lisinopril 5 mg tablet, 30

2457H *Chem mart Lisinopril, CH – LISINOPRIL*, lisinopril 10 mg tablet, 30

2457H *Terry White Chemists Lisinopril, TW – LISINOPRIL*, lisinopril 10 mg tablet, 30

2458J *Chem mart Lisinopril, CH – LISINOPRIL*, lisinopril 20 mg tablet, 30

2458J *Terry White Chemists Lisinopril, TW – LISINOPRIL*, lisinopril 20 mg tablet, 30

8627C *Chem mart Montelukast, CH – MONTELUKAST*, montelukast 4 mg chewable tablet, 28

8627C *Terry White Chemists Montelukast, TW – MONTELUKAST*, montelukast 4 mg chewable tablet, 28

8628D *Chem mart Montelukast, CH – MONTELUKAST*, montelukast 5 mg chewable tablet, 28

8628D *Terry White Chemists Montelukast, TW – MONTELUKAST*, montelukast 5 mg chewable tablet, 28

8449Q *Chem mart Perindopril/Indapamide 4/1.25, CH – PERINDOPRIL + INDAPAMIDE*, perindopril erbumine 4 mg + indapamide hemihydrate 1.25 mg tablet, 30

8449Q *Terry White Chemists Perindopril/Indapamide 4/1.25, TW – PERINDOPRIL + INDAPAMIDE*, perindopril erbumine 4 mg + indapamide hemihydrate 1.25 mg tablet, 30

2833D *Chem mart Pravastatin, CH – PRAVASTATIN*, pravastatin sodium 10 mg tablet, 30

2833D *Terry White Chemists Pravastatin, TW – PRAVASTATIN*, pravastatin sodium 10 mg tablet, 30

9237E *Chem mart Pravastatin, CH – PRAVASTATIN*, pravastatin sodium 10 mg tablet, 30

9237E *Terry White Chemists Pravastatin, TW – PRAVASTATIN*, pravastatin sodium 10 mg tablet, 30

2834E *Chem mart Pravastatin, CH – PRAVASTATIN*, pravastatin sodium 20 mg tablet, 30

2834E *Terry White Chemists Pravastatin, TW – PRAVASTATIN*, pravastatin sodium 20 mg tablet, 30

9238F *Chem mart Pravastatin, CH – PRAVASTATIN*, pravastatin sodium 20 mg tablet, 30

9238F *Terry White Chemists Pravastatin, TW – PRAVASTATIN*, pravastatin sodium 20 mg tablet, 30

8197K *Chem mart Pravastatin, CH – PRAVASTATIN*, pravastatin sodium 40 mg tablet, 30

8197K *Terry White Chemists Pravastatin, TW – PRAVASTATIN*, pravastatin sodium 40 mg tablet, 30

9239G *Chem mart Pravastatin, CH – PRAVASTATIN*, pravastatin sodium 40 mg tablet, 30

9239G *Terry White Chemists Pravastatin, TW – PRAVASTATIN*, pravastatin sodium 40 mg tablet, 30

8829Q *Chem mart Pravastatin, CH – PRAVASTATIN*, pravastatin sodium 80 mg tablet, 30

8829Q *Terry White Chemists Pravastatin, TW – PRAVASTATIN*, pravastatin sodium 80 mg tablet, 30

9240H *Chem mart Pravastatin, CH – PRAVASTATIN*, pravastatin sodium 80 mg tablet, 30

9240H *Terry White Chemists Pravastatin, TW – PRAVASTATIN*, pravastatin sodium 80 mg tablet, 30

1479W *Chem mart Prazosin, CH – PRAZOSIN*, prazosin 1 mg tablet, 100

- 
- 1479W Terry White Chemists Prazosin, TW – **PRAZOSIN**, prazosin 1 mg tablet, 100  
1480X Chem mart Prazosin, CH – **PRAZOSIN**, prazosin 2 mg tablet, 100  
1480X Terry White Chemists Prazosin, TW – **PRAZOSIN**, prazosin 2 mg tablet, 100  
1478T Chem mart Prazosin, CH – **PRAZOSIN**, prazosin 5 mg tablet, 100  
1478T Terry White Chemists Prazosin, TW – **PRAZOSIN**, prazosin 5 mg tablet, 100

**Deletion – Equivalence Indicator**

- 11205R Kalma 0.25, AF – **ALPRAZOLAM**, alprazolam 250 microgram tablet, 10

**Deletion – Note**

- 11205R **ALPRAZOLAM**, alprazolam 250 microgram tablet, 10 (*Kalma 0.25*)  
11187T **ALPRAZOLAM**, alprazolam 500 microgram tablet, 10 (*Alprax 0.5, Kalma 0.5*)  
11186R **ALPRAZOLAM**, alprazolam 1 mg tablet, 10 (*Alprax 1, Kalma 1*)

**Deletion – Restriction**

- 10396E **ADALIMUMAB**, adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes (*Humira*)  
10412B **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (*Humira*)  
10420K **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges (*Humira*)

**Alterations**

**Alteration – Note**

- 10389T **ADALIMUMAB**, adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes (*Humira*)  
10396E **ADALIMUMAB**, adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes (*Humira*)  
10422M **ADALIMUMAB**, adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes (*Humira*)  
10397F **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges (*Humira*)  
10399H **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (*Humira*)  
10400J **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges (*Humira*)  
10404N **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL syringes (*Humira*)  
10412B **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (*Humira*)  
10413C **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges (*Humira*)  
10419J **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (*Humira*)  
10420K **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges (*Humira*)  
8456C **QUETIAPINE**, quetiapine 25 mg tablet, 60 (*APO-Quetiapine, Chem mart Quetiapine, Delucon 25, Kaptan, Pharmacor Quetiapine 25, Quetia 25, Quetiapine AN, Quetiapine GH 25, Quetiapine RBX, Quetiapine Sandoz, Quetiapine-DRLA, Seroquel, Syquet, Terry White Chemists Quetiapine*)

**Alteration – Restriction**

- 9092M **ATOMOXETINE**, atomoxetine 10 mg capsule, 28 (*APO-Atomoxetine, ATOMERRA, Atomoxetine Amneal, Atomoxetine Sandoz, Strattera*)  
9093N **ATOMOXETINE**, atomoxetine 18 mg capsule, 28 (*APO-Atomoxetine, ATOMERRA, Atomoxetine Amneal, Atomoxetine Sandoz, Strattera*)  
9094P **ATOMOXETINE**, atomoxetine 25 mg capsule, 28 (*APO-Atomoxetine, ATOMERRA, Atomoxetine Amneal, Atomoxetine Sandoz, Strattera*)  
9095Q **ATOMOXETINE**, atomoxetine 40 mg capsule, 28 (*APO-Atomoxetine, ATOMERRA, Atomoxetine Amneal, Atomoxetine Sandoz, Strattera*)  
9096R **ATOMOXETINE**, atomoxetine 60 mg capsule, 28 (*APO-Atomoxetine, ATOMERRA, Atomoxetine Amneal, Atomoxetine Sandoz, Strattera*)  
9289X **ATOMOXETINE**, atomoxetine 80 mg capsule, 28 (*APO-Atomoxetine, ATOMERRA, Atomoxetine Amneal, Atomoxetine Sandoz, Strattera*)  
9290Y **ATOMOXETINE**, atomoxetine 100 mg capsule, 28 (*APO-Atomoxetine, ATOMERRA, Atomoxetine Amneal,*

*Atomoxetine Sandoz, Strattera)*

1471K	<b>FLUCONAZOLE</b> , fluconazole 50 mg capsule, 28 ( <i>Diflucan, Dizole 50, Fluconazole Sandoz, Ozole</i> )
1472L	<b>FLUCONAZOLE</b> , fluconazole 100 mg capsule, 28 ( <i>Diflucan, Dizole 100, Fluconazole Sandoz, Ozole</i> )
1475P	<b>FLUCONAZOLE</b> , fluconazole 200 mg capsule, 28 ( <i>APO-Fluconazole, Diflucan, Dizole 200, Fluconazole APOTEX, Fluconazole Sandoz, Fluzole 200, Ozole</i> )
5446P	<b>FLUCONAZOLE</b> , fluconazole 50 mg/5 mL powder for oral liquid, 35 mL ( <i>Diflucan</i> )
1473M	<b>FLUCONAZOLE</b> , fluconazole 100 mg/50 mL injection, 50 mL vial ( <i>Fluconazole Sandoz</i> )
11139G	<b>FLUCONAZOLE</b> , fluconazole 200 mg/100 mL injection, 100 mL bag ( <i>Fluconazole Alphapharm</i> )
1474N	<b>FLUCONAZOLE</b> , fluconazole 200 mg/100 mL injection, 100 mL vial ( <i>Fluconazole Sandoz</i> )
1757L	<b>FLUCONAZOLE</b> , fluconazole 400 mg/200 mL injection, 200 mL bag ( <i>Fluconazole Alphapharm</i> )
10924Y	<b>IMATINIB</b> , imatinib 100 mg capsule, 60 ( <i>CIPLA IMATINIB ADULT, Glivanib, IMATINIB AN, IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX</i> )
10917N	<b>IMATINIB</b> , imatinib 400 mg capsule, 30 ( <i>CIPLA IMATINIB ADULT, Glivanib, IMATINIB AN, IMATINIB-DRLA, Imatinib GH, Imatinib-APOTEX</i> )
9123E	<b>IMATINIB</b> , imatinib 100 mg tablet, 60 ( <i>Glivec, IMATINIB RBX, Imatinib-Teva</i> )
9124F	<b>IMATINIB</b> , imatinib 400 mg tablet, 30 ( <i>Glivec, IMATINIB RBX, Imatinib-Teva</i> )
8456C	<b>QUETIAPINE</b> , quetiapine 25 mg tablet, 60 ( <i>APO-Quetiapine, Chem mart Quetiapine, Delucon 25, Kaptan, Pharmacor Quetiapine 25, Quetia 25, Quetiapine AN, Quetiapine GH 25, Quetiapine RBX, Quetiapine Sandoz, Quetiapine-DRLA, Seroquel, Syquet, Terry White Chemists Quetiapine</i> )

#### **Alteration – Restriction Level**

		<i>From</i>	<i>To</i>
1471K	<b>FLUCONAZOLE</b> , fluconazole 50 mg capsule, 28 ( <i>Diflucan, Dizole 50, Fluconazole Sandoz, Ozole</i> )	restricted	streamlined
1472L	<b>FLUCONAZOLE</b> , fluconazole 100 mg capsule, 28 ( <i>Diflucan, Dizole 100, Fluconazole Sandoz, Ozole</i> )	restricted	streamlined
1475P	<b>FLUCONAZOLE</b> , fluconazole 200 mg capsule, 28 ( <i>APO-Fluconazole, Diflucan, Dizole 200, Fluconazole APOTEX, Fluconazole Sandoz, Fluzole 200, Ozole</i> )	restricted	streamlined
5446P	<b>FLUCONAZOLE</b> , fluconazole 50 mg/5 mL powder for oral liquid, 35 mL ( <i>Diflucan</i> )	restricted	streamlined
1473M	<b>FLUCONAZOLE</b> , fluconazole 100 mg/50 mL injection, 50 mL vial ( <i>Fluconazole Sandoz</i> )	restricted	streamlined
11139G	<b>FLUCONAZOLE</b> , fluconazole 200 mg/100 mL injection, 100 mL bag ( <i>Fluconazole Alphapharm</i> )	restricted	streamlined
1474N	<b>FLUCONAZOLE</b> , fluconazole 200 mg/100 mL injection, 100 mL vial ( <i>Fluconazole Sandoz</i> )	restricted	streamlined
1757L	<b>FLUCONAZOLE</b> , fluconazole 400 mg/200 mL injection, 200 mL bag ( <i>Fluconazole Alphapharm</i> )	restricted	streamlined
10732W	<b>ITRACONAZOLE</b> , itraconazole 50 mg capsule, 60 ( <i>Lozanoc</i> )	restricted	streamlined
8196J	<b>ITRACONAZOLE</b> , itraconazole 100 mg capsule, 60 ( <i>APO-Itraconazole, ITRANOX, Itracap, Sporanox</i> )	restricted	streamlined

#### **Alteration – Manufacturer Code**

		<i>From</i>	<i>To</i>
3107M	<i>Keto-Diastix</i> – <b>GLUCOSE AND KETONE INDICATOR URINE</b> , glucose and ketone indicator urine diagnostic strip, 50	BN	DX
3104J	<i>Diastix</i> – <b>GLUCOSE INDICATOR URINE</b> , glucose indicator urine diagnostic strip, 50	BN	DX
10229J	<i>Venofer</i> – <b>IRON SUCROSE</b> , iron (as sucrose) 100 mg/5 mL injection, 5 x 5 mL ampoules	AS	VL
8807M	<i>Venofer</i> – <b>IRON SUCROSE</b> , iron (as sucrose) 100 mg/5 mL injection, 5 x 5 mL ampoules	AS	VL

#### **Advance Notices**

**1 October 2018**

##### **Deletion – Brand**

8754R	<i>Neocate Advance, SB</i> – <b>AMINO ACID SYNTHETIC FORMULA</b> , amino acid synthetic formula powder for oral liquid, 400 g
-------	---

---

8755T	<i>Neocate Advance, SB</i> – <b>AMINO ACID SYNTHETIC FORMULA</b> , amino acid synthetic formula powder for oral liquid, 400 g
2751T	<i>Ozlodip, RA</i> – <b>AMLODIPINE</b> , amlodipine 5 mg tablet, 30
2752W	<i>Ozlodip, RA</i> – <b>AMLODIPINE</b> , amlodipine 10 mg tablet, 30
8179L	<i>Azastrole, ER</i> – <b>ANASTROZOLE</b> , anastrozole 1 mg tablet, 30
5276Q	<i>Daivobet 50/500 gel, LO</i> – <b>CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE</b> , calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% gel, 30 g
8361C	<i>Xelabine, QA</i> – <b>CAPECITABINE</b> , capecitabine 150 mg tablet, 60
10050Y	<i>basecal 100, VF</i> – <b>CARBOHYDRATES, FAT, VITAMINS, MINERALS, TRACE ELEMENTS AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID</b> , carbohydrates, fat, vitamins, minerals, trace elements and supplemented with arachidonic acid and docosahexaenoic acid providing 100 kilocalories powder for oral liquid, 30 x 2 1.5 g sachets
5509Y	<i>TheraTears, CX</i> – <b>CARMELLOSE SODIUM</b> , carmellose sodium 0.25% (1.5 mg/0.6 mL) eye drops, 24 x 0.6 mL unit doses
5510B	<i>TheraTears, CX</i> – <b>CARMELLOSE SODIUM</b> , carmellose sodium 1% (6 mg/0.6 mL) eye gel, 28 x 0.6 mL unit doses
8823J	<i>TheraTears, CX</i> – <b>CARMELLOSE SODIUM</b> , carmellose sodium 0.25% (1.5 mg/0.6 mL) eye drops, 24 x 0.6 mL unit doses
8824K	<i>TheraTears, CX</i> – <b>CARMELLOSE SODIUM</b> , carmellose sodium 1% (6 mg/0.6 mL) eye gel, 28 x 0.6 mL unit doses
2655R	<i>Rancef, RA</i> – <b>CEFALEXIN</b> , cefalexin 250 mg capsule, 20
3058Y	<i>Rancef, RA</i> – <b>CEFALEXIN</b> , cefalexin 250 mg capsule, 20
3317N	<i>Rancef, RA</i> – <b>CEFALEXIN</b> , cefalexin 250 mg capsule, 20
8220P	<i>Celica, RA</i> – <b>CITALOPRAM</b> , citalopram 20 mg tablet, 28
3138E	<i>Cleocin, FZ</i> – <b>CLINDAMYCIN</b> , clindamycin 150 mg capsule, 24
5057E	<i>Cleocin, FZ</i> – <b>CLINDAMYCIN</b> , clindamycin 150 mg capsule, 24
10026Q	<i>Endoxan, BX</i> – <b>CYCLOPHOSPHAMIDE</b> , cyclophosphamide 50 mg tablet, 50
1270W	<i>Cyrotone, ER</i> – <b>CYPROTERONE</b> , cyproterone acetate 50 mg tablet, 50
8700X	<i>Escicor 10, RA</i> – <b>ESCITALOPRAM</b> , escitalopram 10 mg tablet, 28
8701Y	<i>Escicor 20, RA</i> – <b>ESCITALOPRAM</b> , escitalopram 20 mg tablet, 28
8534E	<i>Ledip, RA</i> – <b>LERCANIDIPINE</b> , lercanidipine hydrochloride 10 mg tablet, 28
8679T	<i>Ledip, RA</i> – <b>LERCANIDIPINE</b> , lercanidipine hydrochloride 20 mg tablet, 28
1324Q	<i>Metoprolol RBX, RA</i> – <b>METOPROLOL TARTRATE</b> , METOPROLOL TARTRATE Tablet 50 mg, 100
2975N	<i>Aptamil Gold+ De-Lact, NU</i> – <b>MILK POWDER LACTOSE FREE FORMULA PREDIGESTED</b> , milk powder lactose free formula predigested powder for oral liquid, 900 g
8370M	<i>ReVia, BQ</i> – <b>NALTREXONE</b> , naltrexone hydrochloride 50 mg tablet, 30
1671Y	<i>Deca-Durabolin, AS</i> – <b>NANDROLONE DECANOATE</b> , nandrolone decanoate 50 mg/mL injection, 1 mL syringe
8694N	<i>Pizaccord, RA</i> – <b>PIOGLITAZONE</b> , pioglitazone 15 mg tablet, 28
8696Q	<i>Pizaccord, RA</i> – <b>PIOGLITAZONE</b> , pioglitazone 45 mg tablet, 28
8508T	<i>Rabeprazole generichealth, GQ</i> – <b>RABEPRAZOLE</b> , rabeprazole sodium 20 mg enteric tablet, 30
8509W	<i>Rabeprazole generichealth, GQ</i> – <b>RABEPRAZOLE</b> , rabeprazole sodium 20 mg enteric tablet, 30
1849H	<i>Sumatriptan RBX, RA</i> – <b>SUMATRIPTAN</b> , sumatriptan 50 mg tablet, 4
5546X	<i>Nyogel, AS</i> – <b>TIMOLOL</b> , timolol 0.1% eye gel, 5 g
8803H	<i>Nyogel, AS</i> – <b>TIMOLOL</b> , timolol 0.1% eye gel, 5 g

### 1 December 2018

#### Deletion – Brand

10013B	<i>Benzotropine Omega, FK</i> – <b>BENZATROPINE</b> , benzatropine mesilate 2 mg/2 mL injection, 10 x 2 mL vials
10027R	<i>Benzotropine Omega, FK</i> – <b>BENZATROPINE</b> , benzatropine mesilate 2 mg/2 mL injection, 10 x 2 mL vials
8362D	<i>Xeloda, RO</i> – <b>CAPECITABINE</b> , capecitabine 500 mg tablet, 120

---

### 1 March 2019

#### Deletion – Brand

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

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

### 1 September 2019

#### Deletion – Brand

1711C *Hypurin Isophane, AS* – **INSULIN ISOPHANE BOVINE**, insulin isophane bovine 100 units/mL injection, 1 x 10 mL vial

1713E *Hypurin Neutral, AS* – **INSULIN NEUTRAL BOVINE**, insulin neutral bovine 100 units/mL injection, 1 x 10 mL vial

## Highly Specialised Drugs Program (Private Hospital)

### Additions

#### Addition – Item

11445J **INFLIXIMAB**, infliximab 100 mg injection, 1 vial (*Remicade*)

11450P **INFLIXIMAB**, infliximab 100 mg injection, 1 vial (*Inflixtra, Renflexis*)

#### Addition – Brand

6328C *Tacrograf, RW* – **TACROLIMUS**, tacrolimus 500 microgram capsule, 100

6216E *Tacrograf, RW* – **TACROLIMUS**, tacrolimus 1 mg capsule, 100

6217F *Tacrograf, RW* – **TACROLIMUS**, tacrolimus 5 mg capsule, 50

### Alterations

#### Alteration – Note

9612X **INFLIXIMAB**, infliximab 100 mg injection, 1 vial (*Inflixtra, Remicade, Renflexis*)

#### Alteration – Restriction

9612X **INFLIXIMAB**, infliximab 100 mg injection, 1 vial (*Inflixtra, Remicade, Renflexis*)

## Highly Specialised Drugs Program (Public Hospital)

### Additions

#### Addition – Item

11448M **INFLIXIMAB**, infliximab 100 mg injection, 1 vial (*Remicade*)

11449N **INFLIXIMAB**, infliximab 100 mg injection, 1 vial (*Inflixtra, Renflexis*)

#### Addition – Brand

9558C *Tacrograf, RW* – **TACROLIMUS**, tacrolimus 500 microgram capsule, 100

9560E *Tacrograf, RW* – **TACROLIMUS**, tacrolimus 1 mg capsule, 100

9561F *Tacrograf, RW* – **TACROLIMUS**, tacrolimus 5 mg capsule, 50

### Alterations

#### Alteration – Note

5755X **INFLIXIMAB**, infliximab 100 mg injection, 1 vial (*Inflixtra, Remicade, Renflexis*)

#### Alteration – Restriction

5755X **INFLIXIMAB**, infliximab 100 mg injection, 1 vial (*Inflixtra, Remicade, Renflexis*)

## Highly Specialised Drugs Program (Community Access)

### 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

## Growth Hormone Program

### Advance Notices

**1 January 2019**

**Deletion – Brand**

- 10444Q *Genotropin, PF* – **SOMATROPIN**, somatropin 12 mg injection [1 cartridge] (& inert substance diluent [1 mL cartridge]), 1 pack  
10499N *Genotropin, PF* – **SOMATROPIN**, somatropin 12 mg injection [1 cartridge] (& inert substance diluent [1 mL cartridge]), 1 pack  
6312F *Genotropin, PF* – **SOMATROPIN**, somatropin 12 mg injection [1 cartridge] (& inert substance diluent [1 mL cartridge]), 1 pack

## Repatriation Pharmaceutical Benefits

### Deletions

**Deletion – Item**

- 4007X **KETOCONAZOLE**, ketoconazole 2% shampoo, 100 mL (*Sebizole*)

**Deletion – Brand**

- 2194L *Chem mart Alendronate Plus D3 70 mg/70 mcg, CH* – **ALENDRONATE + COLECALCIFEROL**, alendronate 70 mg + colecalciferol 70 microgram tablet, 4  
2194L *Terry White Chemists Alendronate Plus D3 70 mg/70 mcg, TW* – **ALENDRONATE + COLECALCIFEROL**, alendronate 70 mg + colecalciferol 70 microgram 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  
2224C *Terry White Chemists Alendronate Plus D3 70 mg/140 mcg, TW* – **ALENDRONATE + COLECALCIFEROL**, alendronate 70 mg + colecalciferol 140 microgram (5600 units) tablet, 4

### Advance Notices

**1 October 2018**

**Deletion – Brand**

- 4035J *Albalon Liquifilm, AG* – **NAPHAZOLINE**, naphazoline hydrochloride 0.1% eye drops, 15 mL  
4032F *Albalon-A, AG* – **NAPHAZOLINE + ANTAZOLINE**, naphazoline hydrochloride 0.05% + antazoline phosphate 0.5% eye drops, 15 mL  
4390C *Wartec Cream, GK* – **PODOPHYLLOTOXIN**, podophyllotoxin 0.15% cream, 5 g  
4586J *Silaran, RA* – **SILDENAFIL**, sildenafil 100 mg tablet, 4  
4405W *Polytar, GK* – **TAR + CADE OIL + COAL TAR + ARACHIS OIL EXTRACT OF COAL TAR**, tar 0.3% (300 microgram/mL) + cade oil 0.03% (300 microgram/mL) + coal tar 0.01% (100 microgram/mL) + arachis oil extract of coal tar 0.3% (3 mg/mL) lotion, 300 mL

# General Pharmaceutical Benefits

## ▪ ADALIMUMAB

### Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only. A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time. For paediatric patients with Crohn disease, infliximab is PBS-subsidised for moderate to severe disease while adalimumab is PBS-subsidised for severe disease.

From 1 August 2015, under the PBS, patients commencing on adalimumab will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when switching to infliximab. Patients on infliximab will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine but will need to meet a PCDAI score of greater than or equal to 40 when switching to adalimumab. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine 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 biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine 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 biological medicine therapy after 1 August 2015.

(a) Initial treatment.

Applications for initial treatment should be made where:

- i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 treatment (new patient or Re-commencement of treatment after more than 5 years break in therapy); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 treatment (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Switching therapy' below]; or
- (iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 treatment (Change or Re-commencement of treatment after a break in therapy of less than 5 years).

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 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy 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 first and subsequent continuing courses of PBS-subsidised biological medicine therapy, 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 should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent Continuing treatment restrictions with that drug 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 therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition. Patients on infliximab may swap to adalimumab within the same treatment cycle provided that their disease severity has progressed to severe disease (i.e. they have a current PCDAI score of 40 or more).

A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice 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 of the PCDAI submitted with the first authority application for a biological medicine. 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.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to assess response to all subsequent treatments.

(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.

Patients must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months immediately prior to the time the PCDAI score is measured.

**Note** Special Pricing Arrangements apply.

**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).

Written applications for authority approval for sufficient therapy to complete the balance of supply should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe Crohn disease

Treatment Phase: Balance of supply for paediatric patient

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under Initial 1 (new patient or patient recommencing treatment after break of more than 5 years) or Initial 2 (change or recommencement of treatment after a break of less than 5 years) or Initial 3 (grandfathered patients) or Continuing treatment to complete the maximum duration of treatment specified in the relevant treatment phase, **AND**
- The treatment must provide no more than the balance of up to 16 weeks of therapy (new patients or change/re-commencement patients; Initial 1 or Initial 2) or 24 weeks of therapy (Continuing patients or Grandfathered patients).

#### **Treatment criteria:**

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

#### **adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes**

10422M	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	..	1269.60	39.50	Humira [VE]

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

10400J	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	..	1269.60	39.50	Humira [VE]

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

10399H	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	..	1269.60	39.50	Humira [VE]

## ■ ADALIMUMAB

### Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only. A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time. For paediatric patients with Crohn disease, infliximab is PBS-subsidised for moderate to severe disease while adalimumab is PBS-subsidised for severe disease.

From 1 August 2015, under the PBS, patients commencing on adalimumab will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when switching to infliximab. Patients on infliximab will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine but will need to meet a PCDAI score of greater than or equal to 40 when switching to adalimumab.

Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who has received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine 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 biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine 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 biological medicine therapy after 1 August 2015.

(a) Initial treatment.

Applications for initial treatment should be made where:

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

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 treatment (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Switching therapy' below]; or

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

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 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy 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 first and subsequent continuing courses of PBS-subsidised biological medicine therapy, 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 should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent Continuing treatment restrictions with that drug 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) Switching therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may switch if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition. Patients on infliximab may switch to adalimumab within the same treatment cycle provided that their disease severity has progressed to severe disease (i.e. they have a current PCDAI score of 40 or more).

A patient cannot switch to a biological medicine if they have failed to respond to prior treatment with that drug twice 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 of the PCDAI submitted with the first authority application for a biological medicine. 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.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to assess response to all subsequent treatments.

(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.

Patients must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months immediately prior to the time the PCDAI score is measured.

**Note** Special Pricing Arrangements apply.

**Note** No applications for increased maximum quantities will be authorised.

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

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

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

Severe Crohn disease

Treatment Phase: Continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

#### **Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug as defined as a reduction in PCDAI Score by at least 15 points as compared to baseline and a total of PCDAI score of 40 points or less with the PCDAI assessment being no more than 1 month old at the time of application.

#### **Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

#### **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)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

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

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))] which includes the following:

(i) the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.

The PCDAI 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, a PCDAI 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.

The 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 the Department of Human Services 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 criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Patients are eligible to receive continuing treatment with this drug 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) and authorised through the Balance of Supply treatment phase PBS restriction.

**adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes**

10396E	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 cartridges**

10420K	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**

10412B	Max. Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1		5	..	1269.60	39.50	Humira [VE]

**■ ADALIMUMAB****Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only. A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time. For paediatric patients with Crohn disease, infliximab is PBS-subsidised for moderate to severe disease while adalimumab is PBS-subsidised for severe disease.

From 1 August 2015, under the PBS, patients commencing on adalimumab will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to infliximab. Patients on infliximab will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine but will need to meet a PCDAI score of greater than or equal to 40 when swapping to adalimumab.

Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine 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 biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine 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 biological medicine therapy after 1 August 2015.

(a) Initial treatment.

Applications for initial treatment should be made where:

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

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 treatment (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

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

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 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy 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 first and subsequent continuing courses of PBS-subsidised biological medicine therapy, 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 should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent Continuing

treatment restrictions with that drug 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 therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition. Patients on infliximab may swap to adalimumab within the same treatment cycle provided that their disease severity has progressed to severe disease (i.e. they have a current PCDAI score of 40 or more).

A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice 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 of the PCDAI submitted with the first authority application for a biological medicine. 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.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to assess response to all subsequent treatments.

(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.

Patients must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months immediately prior to the time the PCDAI score is measured.

**Note** Special Pricing Arrangements apply.

**Note** No applications for increased maximum quantities will be authorised.

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

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

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

Severe Crohn disease

Treatment Phase: Initial treatment (new paediatric patient) of Crohn disease in a paediatric patient assessed by PCDAI (Initial 1)

#### **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, consultant physician, paediatrician or specialist paediatric gastroenterologist, **AND**
- Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, **AND**
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment and which is no more than 1 month old at the time of application.

#### **Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

#### **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)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

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

(a) two completed authority prescription forms; and

(b) a completed paediatric Crohn Disease PBS Authority Application -Supporting Information Form [may be downloaded from the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))] which includes the following:

(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy] or dates of enteral nutrition; and

(iii) the signed patient or guardian 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 specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details 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, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au)).

A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) will be authorised.

Two completed authority prescriptions should be submitted with every initial application for this drug. For patients weighing 40 kg or greater: one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats. For patients weighing less than 40 kg: one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

If fewer than 2 repeats (for patients 40 kg or greater) or 3 repeats (for patients less than 40 kg) are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with this drug 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) and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

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

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted 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 time-frames, the patient will be deemed to have failed to respond to treatment with this drug.

It is recommended that an application for continuing treatment is posted 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 continuation criterion for PBS-subsidised treatment with this drug.

#### **Authority required**

Severe Crohn disease

Treatment Phase: Change or re-commencement of treatment of Crohn disease in a paediatric patient assessed by PCDAI (Initial 2)

#### **Clinical criteria:**

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must in this treatment cycle, have received prior PBS-subsidised treatment with this drug for this condition; OR
- Patient must in this treatment cycle, have received prior PBS-subsidised treatment with infliximab for this condition and have a current PCDAI score of 40 or greater, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

#### **Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

#### **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)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

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 timeframes 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 the Department of Human Services 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.

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

(a) two completed authority prescription form; and

(b) a completed paediatric Crohn Disease PBS Authority Application -Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following:

- (i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) Score calculation sheet; and
- (ii) details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

Two completed authority prescriptions should be submitted with every initial application for this drug. For patients weighing 40 kg or greater: one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats. For patients weighing less than 40 kg: one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

If fewer than 2 repeats (for patients 40 kg or greater) or 3 repeats (for patients less than 40 kg) are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with this drug 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) and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

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

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted 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 time-frames, the patient will be deemed to have failed to respond to treatment with this drug.

It is recommended that an application for continuing treatment is posted 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 continuation criterion for PBS-subsidised treatment with this drug.

#### adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes

10389T	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1		3	..	1269.60	39.50	Humira [VE]

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

10397F	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

10413C	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

10419J	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

10404N	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1		..	..	3606.66	39.50	Humira [VE]

### ■ ATOMOXETINE

**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)**

##### **7876**

Attention deficit hyperactivity disorder

Treatment Phase: Initial treatment

#### **Treatment criteria:**

- Must be treated by a paediatrician or psychiatrist.

#### **Clinical criteria:**

- The condition must be or have been diagnosed according to the DSM-5 criteria, **AND**
- Patient must have a contraindication to dexamfetamine, methylphenidate or lisdexamfetamine as specified in TGA-approved product information; OR
- Patient must have a comorbid mood disorder that has developed or worsened as a result of dexamfetamine, methylphenidate or lisdexamfetamine treatment and is of a severity necessitating treatment withdrawal; OR
- Patient must be at an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal if given a stimulant treatment with another agent; OR
- Patient must have experienced adverse reactions of a severity necessitating permanent treatment withdrawal following treatment with dexamfetamine, methylphenidate and lisdexamfetamine (not simultaneously).

#### **Population criteria:**

- Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

#### **Authority required (STREAMLINED)**

##### **7890**

Attention deficit hyperactivity disorder

Treatment Phase: Continuing treatment

**Clinical criteria:**

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

**atomoxetine 80 mg capsule, 28**

9289X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	90.54	39.50	<sup>a</sup> APO-Atomoxetine [TX] <sup>a</sup> Atomoxetine Amneal [EA] <sup>a</sup> Strattera [LY]	<sup>a</sup> ATOMERRA [RW] <sup>a</sup> Atomoxetine Sandoz [SZ]

**atomoxetine 10 mg capsule, 28**

9092M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*133.19	39.50	<sup>a</sup> APO-Atomoxetine [TX] <sup>a</sup> Atomoxetine Amneal [EA] <sup>a</sup> Strattera [LY]	<sup>a</sup> ATOMERRA [RW] <sup>a</sup> Atomoxetine Sandoz [SZ]

**atomoxetine 40 mg capsule, 28**

9095Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*133.19	39.50	<sup>a</sup> APO-Atomoxetine [TX] <sup>a</sup> Atomoxetine Amneal [EA] <sup>a</sup> Strattera [LY]	<sup>a</sup> ATOMERRA [RW] <sup>a</sup> Atomoxetine Sandoz [SZ]

**atomoxetine 18 mg capsule, 28**

9093N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*133.19	39.50	<sup>a</sup> APO-Atomoxetine [TX] <sup>a</sup> Atomoxetine Amneal [EA] <sup>a</sup> Strattera [LY]	<sup>a</sup> ATOMERRA [RW] <sup>a</sup> Atomoxetine Sandoz [SZ]

**atomoxetine 25 mg capsule, 28**

9094P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*133.19	39.50	<sup>a</sup> APO-Atomoxetine [TX] <sup>a</sup> Atomoxetine Amneal [EA] <sup>a</sup> Strattera [LY]	<sup>a</sup> ATOMERRA [RW] <sup>a</sup> Atomoxetine Sandoz [SZ]

**atomoxetine 100 mg capsule, 28**

9290Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	90.54	39.50	<sup>a</sup> APO-Atomoxetine [TX] <sup>a</sup> Atomoxetine Amneal [EA] <sup>a</sup> Strattera [LY]	<sup>a</sup> ATOMERRA [RW] <sup>a</sup> Atomoxetine Sandoz [SZ]

**atomoxetine 60 mg capsule, 28**

9096R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*133.19	39.50	<sup>a</sup> APO-Atomoxetine [TX] <sup>a</sup> Atomoxetine Amneal [EA] <sup>a</sup> Strattera [LY]	<sup>a</sup> ATOMERRA [RW] <sup>a</sup> Atomoxetine Sandoz [SZ]

▪ **BARICITINIB**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

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

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

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

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

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

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

---

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

(a) Initial treatment.

Applications for initial treatment should be made where:

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

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

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

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

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

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

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

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that 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.

Abatacept patients:

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

Rituximab patients:

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

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy

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

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

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

Abatacept:

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

Rituximab:

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

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

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

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

---

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

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

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

**Note** Special Pricing Arrangements apply.

---

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

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

#### **Clinical criteria:**

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

#### **Population criteria:**

- Patient must be aged 18 years or older.

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

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

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

(1) a completed authority prescription form; and

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

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

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

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

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

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

Severe active rheumatoid arthritis

Treatment Phase: Continuing and Initial 3 (Grandfathered patients) treatment - balance of supply

#### **Treatment criteria:**

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

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; OR
- Patient must have received insufficient treatment with this drug to complete 24 weeks of treatment under the Initial 3 (Grandfathered patients), **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

#### **Population criteria:**

- Patient must be aged 18 years or older.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

---

### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (Grandfathered patients)

#### **Treatment criteria:**

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

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have previously received non-PBS-subsidised therapy with this drug for this condition prior to 1 September 2018, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- Patient must have failed to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; OR
- Patient must have failed to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not have failed more than 4 PBS-subsidised bDMARD treatments for this condition in a lifetime, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

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

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

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

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

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

An adequate response to treatment is defined as:

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

AND either of the following:

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

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  
Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

All applications for treatment with this drug for this condition under this restriction must include baseline joint count and ESR and/or CRP as determined at the completion of a 6 month intensive DMARD trial but prior to ceasing DMARD therapy, and measurement of response to the prior course of non-PBS-subsidised therapy with this drug. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course.

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

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

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

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

**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](http://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

### baricitinib 2 mg tablet, 28

11442F	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1		5	..	1267.64	39.50	Olumiant [LY]

### baricitinib 4 mg tablet, 28

11443G	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1		5	..	1267.64	39.50	Olumiant [LY]

## ■ BARICITINIB

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

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

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

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

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

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

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

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

(a) Initial treatment.

Applications for initial treatment should be made where:

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

---

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

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

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

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

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that 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.

**Abatacept patients:**

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

**Rituximab patients:**

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

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

**Rituximab patients:**

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy

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

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

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

**Abatacept:**

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

**Rituximab:**

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

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

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

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

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20

active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

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

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

**Note** Special Pricing Arrangements apply.

---

#### **Authority required**

Severe active rheumatoid arthritis

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

#### **Treatment criteria:**

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

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Clinical criteria:**

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

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

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

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

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

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

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

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

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

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

---

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Severe active rheumatoid arthritis

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

#### **Treatment criteria:**

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

#### **Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

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

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

(a) a completed authority prescription form and

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

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

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

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

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

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

An adequate response to treatment is defined as:

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

AND either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
- (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
- (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

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

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

Severe active rheumatoid arthritis

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

#### **Treatment criteria:**

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

#### **Clinical criteria:**

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

#### **Population criteria:**

- Patient must be aged 18 years or older.

**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).

#### **baricitinib 2 mg tablet, 28**

11437Y	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1		3	..	1267.64	39.50	Olumiant [LY]

#### **baricitinib 4 mg tablet, 28**

11447L	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1		3	..	1267.64	39.50	Olumiant [LY]

### **■ FLUCONAZOLE**

#### **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.

#### **Authority required (STREAMLINED)**

#### **6002**

Cryptococcal meningitis

#### **Authority required (STREAMLINED)**

#### **5978**

Cryptococcal meningitis

#### **Clinical criteria:**

- The treatment must be maintenance therapy, **AND**
- Patient must be immunosuppressed.

#### **Authority required (STREAMLINED)**

#### **6023**

Oropharyngeal candidiasis

#### **Clinical criteria:**

- Patient must be immunosuppressed.

#### **Authority required (STREAMLINED)**

#### **5989**

Oesophageal candidiasis

#### **Clinical criteria:**

- Patient must be immunosuppressed.

#### **Authority required (STREAMLINED)**

#### **6030**

Oropharyngeal candidiasis

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must be immunosuppressed.

**Authority required (STREAMLINED)****7898**

Fungal infection

**Clinical criteria:**

- The condition must be serious or life-threatening.

**fluconazole 100 mg/50 mL injection, 50 mL vial**

1473M	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	7		..	..	*21.36	22.59	Fluconazole Sandoz [SZ]

**fluconazole 400 mg/200 mL injection, 200 mL bag**

1757L	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1		..	..	15.57	16.80	Fluconazole Alphapharm [AF]

**FLUCONAZOLE****Note** Not for use in vulvovaginal candida infections.**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.

**Authority required (STREAMLINED)****6002**

Cryptococcal meningitis

**Authority required (STREAMLINED)****5978**

Cryptococcal meningitis

**Clinical criteria:**

- The treatment must be maintenance therapy, **AND**
- Patient must be immunosuppressed.

**Authority required (STREAMLINED)****6023**

Oropharyngeal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed.

**Authority required (STREAMLINED)****5989**

Oesophageal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed.

**Authority required (STREAMLINED)****6030**

Oropharyngeal candidiasis

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must be immunosuppressed.

**Authority required (STREAMLINED)****7898**

Fungal infection

**Clinical criteria:**

- The condition must be serious or life-threatening.

**fluconazole 50 mg capsule, 28**

1471K	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1		5	..	21.97	23.20	<sup>a</sup> Dizole 50 [AF] <sup>a</sup> Ozole [RA]	<sup>a</sup> Fluconazole Sandoz [SZ]
				<sup>b</sup> 6.00	27.97	23.20	<sup>a</sup> Diflucan [PF]	

**fluconazole 100 mg capsule, 28**

1472L	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1		5	..	32.05	33.28	<sup>a</sup> Diflucan [PF] <sup>a</sup> Fluconazole Sandoz [SZ]	<sup>a</sup> Dizole 100 [AF] <sup>a</sup> Ozole [RA]

**fluconazole 200 mg capsule, 28**

1475P	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	1		5	..	51.70	39.50	<sup>a</sup> APO-Fluconazole [TX] <sup>a</sup> Dizole 200 [AF]	<sup>a</sup> Diflucan [PF] <sup>a</sup> Fluconazole APOTEX [GX]

▪ **FLUCONAZOLE**

**Note** Not for use in vulvovaginal candida infections.

**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.

**Authority required (STREAMLINED)**

**6006**

Cryptococcal meningitis

**Clinical criteria:**

- Patient must be unable to take a solid dose form of fluconazole.

**Authority required (STREAMLINED)**

**6045**

Cryptococcal meningitis

**Clinical criteria:**

- The treatment must be maintenance therapy, **AND**
- Patient must be immunosuppressed, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

**Authority required (STREAMLINED)**

**6031**

Oropharyngeal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

**Authority required (STREAMLINED)**

**6046**

Oesophageal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

**Authority required (STREAMLINED)**

**6032**

Oropharyngeal candidiasis

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must be immunosuppressed, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

**Authority required (STREAMLINED)**

**7934**

Fungal infection

**Clinical criteria:**

- The condition must be serious or life-threatening, **AND**
- Patient must be unable to take a solid dose form of fluconazole.

**fluconazole 50 mg/5 mL powder for oral liquid, 35 mL**

5446P

Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	..	..		#67.72	39.50	Diflucan [PF]

NP

▪ **FLUCONAZOLE**

**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.

**Note** Pharmaceutical benefits that have the forms fluconazole 200 mg/100 mL injection, 100 mL vial and fluconazole 200 mg/100 mL injection, 100 mL bag are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

**6956**

Cryptococcal meningitis

**Authority required (STREAMLINED)**

**6978**

Cryptococcal meningitis

**Clinical criteria:**

- The treatment must be maintenance therapy, **AND**
- Patient must be immunosuppressed.

**Authority required (STREAMLINED)**

**6974**

Oropharyngeal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed.

**Authority required (STREAMLINED)**

**6969**

Oesophageal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed.

**Authority required (STREAMLINED)**

**6965**

Oropharyngeal candidiasis

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must be immunosuppressed.

**Authority required (STREAMLINED)**

**7897**

Fungal infection

**Clinical criteria:**

- The condition must be serious or life-threatening.

**fluconazole 200 mg/100 mL injection, 100 mL vial**

	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1474N	7		..	..	*46.63	39.50	<sup>a</sup> Fluconazole Sandoz [SZ]

NP

**fluconazole 200 mg/100 mL injection, 100 mL bag**

	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11139G	7		..	..	*46.63	39.50	<sup>a</sup> Fluconazole Alphapharm [AF]

NP

▪ **GUANFACINE**

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**7889**

Attention deficit hyperactivity disorder

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a paediatrician or psychiatrist.

**Clinical criteria:**

- The condition must be or have been diagnosed according to the DSM-5 criteria, **AND**
- Patient must have a contraindication to dexamfetamine, methylphenidate or lisdexamfetamine as specified in TGA-approved product information; OR
- Patient must have a comorbid mood disorder that has developed or worsened as a result of dexamfetamine, methylphenidate or lisdexamfetamine treatment and is of a severity necessitating treatment withdrawal; OR
- Patient must be at an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal if given a stimulant treatment with another agent; OR
- Patient must have experienced adverse reactions of a severity necessitating permanent treatment withdrawal following treatment with dexamfetamine, methylphenidate and lisdexamfetamine (not simultaneously).

**Population criteria:**

- Patient must be or have been diagnosed between the ages of 6 and 17 years inclusive.

**Authority required (STREAMLINED)**

**7874**

Attention deficit hyperactivity disorder

Treatment Phase: Continuing treatment

**Clinical criteria:**

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

**guanfacine 4 mg modified release tablet, 28**

	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11441E	1		5	..	123.96	39.50	Intuniv [Z]

**guanfacine 2 mg modified release tablet, 28**

	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11451Q	1		5	..	123.96	39.50	Intuniv [Z]

---

**guanfacine 3 mg modified release tablet, 28**

11440D	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1		5	..	123.96	39.50	Intuniv [Zi]

**guanfacine 1 mg modified release tablet, 28**

11452R	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1		5	..	123.96	39.50	Intuniv [Zi]

**■ IMATINIB**

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**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](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

**Note** No applications for increased repeats will be authorised.

---

**Authority required**

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be newly diagnosed, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- The treatment must be for induction and consolidation therapy, **AND**
- The treatment must be in combination with chemotherapy or corticosteroids.

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

- (a) a completed authority prescription form; and
- (b) a completed Acute Lymphoblastic Leukaemia Imatinib PBS Authority Application - Supporting Information Form; and
- (c) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided); and
- (d) a signed patient acknowledgement

**Authority required**

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be expressing the Philadelphia chromosome; OR
  - The condition must have the transcript BCR-ABL, **AND**
  - Patient must have previously received treatment with this drug for this condition under Imatinib Compassionate Program.
- The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Acute Lymphoblastic Leukaemia Imatinib PBS Authority Application - Supporting Information Form; and
- (c) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided); and
- (d) a signed patient acknowledgement

**Authority required**

Acute lymphoblastic leukaemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- The treatment must be for maintenance of first complete remission, **AND**
- The treatment must be in combination with chemotherapy or corticosteroids.

Imatinib is available with a lifetime maximum of 24 months for continuing treatment with imatinib therapy for patients with acute lymphoblastic leukaemia reimbursed through the PBS.

**Note** Any queries concerning the arrangements to prescribe this drug beyond 24 months 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).

### imatinib 400 mg capsule, 30

10917N	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1		2	..	2488.04	39.50	<sup>a</sup> CIPLA IMATINIB ADULT [LR] <sup>a</sup> IMATINIB AN [JO] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Glivanib [JU] <sup>a</sup> Imatinib-APOTEX [TX] <sup>a</sup> Imatinib GH [GQ]

### imatinib 400 mg tablet, 30

9124F	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1		2	..	2488.04	39.50	<sup>a</sup> Glivec [AF] <sup>a</sup> Imatinib-Teva [TB]	<sup>a</sup> IMATINIB RBX [RA]

## ■ IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**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](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

**Note** No applications for increased repeats will be authorised.

#### Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- Patient must be newly diagnosed, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- The treatment must be for induction and consolidation therapy, **AND**
- The treatment must be in combination with chemotherapy or corticosteroids.

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

- (a) a completed authority prescription form; and
- (b) a completed Acute Lymphoblastic Leukaemia Imatinib PBS Authority Application - Supporting Information Form; and
- (c) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided); and
- (d) a signed patient acknowledgement

#### Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- The condition must be expressing the Philadelphia chromosome; OR
  - The condition must have the transcript BCR-ABL, **AND**
  - Patient must have previously received treatment with this drug for this condition under Imatinib Compassionate Program.
- The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Acute Lymphoblastic Leukaemia Imatinib PBS Authority Application - Supporting Information Form; and
- (c) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided); and
- (d) a signed patient acknowledgement

#### Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**

- The treatment must be for maintenance of first complete remission, **AND**
  - The treatment must be in combination with chemotherapy or corticosteroids.
- Imatinib is available with a lifetime maximum of 24 months for continuing treatment with imatinib therapy for patients with acute lymphoblastic leukaemia reimbursed through the PBS.

**Note** Any queries concerning the arrangements to prescribe this drug beyond 24 months 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).

### imatinib 100 mg tablet, 60

9123E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1286.82	39.50	<sup>a</sup> Glivec [AF] <sup>a</sup> Imatinib-Teva [TB]	<sup>a</sup> IMATINIB RBX [RA]

### imatinib 100 mg capsule, 60

10924Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1286.82	39.50	<sup>a</sup> CIPLA IMATINIB ADULT [LR] <sup>a</sup> IMATINIB AN [JO] <sup>a</sup> IMATINIB-DRLA [RZ]	<sup>a</sup> Glivanib [JU] <sup>a</sup> Imatinib-APOTEX [TX] <sup>a</sup> Imatinib GH [GQ]

## ■ ITRACONAZOLE

**Note** Not for use in vulvovaginal candida infections.

**Note** One capsule of itraconazole 50 mg (Lozanoc) is therapeutically equivalent to one 100 mg capsule of conventional itraconazole (Sporanox). The recommended dose of Lozanoc is therefore half the recommended dose for Sporanox. Lozanoc 50 mg capsules and Sporanox 100 mg capsules are not interchangeable.

**Note** Not for use in superficial mycoses

**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.

**Authority required (STREAMLINED)**

**6022**

Systemic aspergillosis

**Authority required (STREAMLINED)**

**6005**

Systemic sporotrichosis

**Authority required (STREAMLINED)**

**6057**

Systemic histoplasmosis

**Authority required (STREAMLINED)**

**5988**

Disseminated pulmonary histoplasmosis infection

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

- Patient must be diagnosed with acquired immunodeficiency syndrome (AIDS).

**Authority required (STREAMLINED)**

**6037**

Chronic pulmonary histoplasmosis infection

Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**

- Patient must be diagnosed with acquired immunodeficiency syndrome (AIDS).

**Authority required (STREAMLINED)**

**6016**

Oropharyngeal candidiasis

**Clinical criteria:**

- Patient must be immunosuppressed.

**Authority required (STREAMLINED)**


**6035**

Oesophageal candidiasis


**Clinical criteria:**

- Patient must be immunosuppressed.

### itraconazole 50 mg capsule, 60

10732W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	128.90	39.50	Lozanoc [YN]

### itraconazole 100 mg capsule, 60

8196J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	128.90	39.50	<sup>a</sup> APO-Itraconazole [TX] <sup>a</sup> ITRANOX [RW]	<sup>a</sup> Itracap [AF] <sup>a</sup> Sporanox [JC]

## ▪ LONG CHAIN TRIGLYCERIDES

**Note** Carbzero is not nutritionally complete and is not intended for use as a sole source of nutrition.

### Restricted benefit

Ketogenic diet

#### **Clinical criteria:**

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

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

### long chain triglycerides oral liquid, 15 x 225 mL bottles

11438B	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..		*219.03	39.50	Carbzero [VF]

## ▪ MEDIUM CHAIN TRIGLYCERIDES

**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)

**6147**

Ketogenic diet

#### **Clinical criteria:**

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

### Authority required (STREAMLINED)

**6191**

Dietary management of conditions requiring a source of medium chain triglycerides

#### **Clinical criteria:**

- Patient must have chylous ascites; OR
- Patient must have chylothorax; OR
- Patient must have hyperlipoproteinaemia type 1; OR
- Patient must have long chain fatty acid oxidation disorders; OR
- Patient must have fat malabsorption due to liver disease; OR
- Patient must have fat malabsorption due to short gut syndrome; OR
- Patient must have fat malabsorption due to cystic fibrosis; OR
- Patient must have fat malabsorption due to gastrointestinal disorders.

### medium chain triglycerides oral liquid, 15 x 225 mL bottles

11444H	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..		*268.83	39.50	Betaquik [VF]

## ▪ PERFLUOROHEXYLOCTANE

**Note** The in-use shelf life of Novatears is 6 months from the date of opening.

### Authority required (STREAMLINED)

**6172**

Severe dry eye syndrome

#### **Clinical criteria:**

- Patient must be sensitive to preservatives in multi-dose eye drops.

### perfluorohexyloctane 100% eye drops, 3 mL

11439C	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>OP</b>	1	5	..		32.83	34.06	Novatears [AE]

### perfluorohexyloctane 100% eye drops, 3 mL

11446K	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..		32.83	34.06	Novatears [AE]

## ▪ PONATINIB

### Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- Patient must have failed prior treatment with PBS-subsidised dasatinib for this condition; OR
- Patient must have developed intolerance to PBS-subsidised dasatinib of a severity requiring treatment withdrawal, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

---

Failure of treatment with dasatinib is defined as either:

1. Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with PBS-subsidised dasatinib for this condition; or
2. Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by PBS-subsidised dasatinib for this condition; or
3. Rising levels of BCR-ABL1 transcript on two consecutive occasions in a patient in complete remission while being treated with PBS-subsidised dasatinib for this condition.

Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells bearing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission; OR rising levels of BCR-ABL1 transcript on two consecutive occasions in a patient in complete remission while being treated with PBS-subsidised dasatinib for this condition.

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

1. a completed authority prescription form; and
2. a completed Acute Lymphoblastic Leukaemia ponatinib PBS Authority Application - Supporting Information Form; and
3. a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. The date of the relevant pathology report(s) need(s) to be provided; or
4. pathology reports documenting rising levels of BCR-ABL1 transcript on two consecutive occasions in a patient in complete remission while being treated with PBS-subsidised dasatinib for this condition. The date of the relevant pathology report(s) need(s) to be provided

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

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

Acute lymphoblastic leukaemia

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 therapy for this condition, **AND**
- Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition.

**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**

Acute lymphoblastic leukaemia

Treatment Phase: Grandfather treatment

**Clinical criteria:**

- Patient must have previously received non-PBS-subsidised therapy with this drug for this condition prior to 1 September 2018, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- Patient must have failed prior treatment with PBS-subsidised dasatinib for this condition; OR
- Patient must have developed intolerance to PBS-subsidised dasatinib of a severity requiring treatment withdrawal, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Failure of treatment with dasatinib is defined as either:

1. Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with PBS-subsidised dasatinib for this condition; or
2. Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by PBS-subsidised dasatinib for this condition; or
3. Rising levels of BCR-ABL1 transcript on two consecutive occasions in a patient in complete remission while being treated with PBS-subsidised dasatinib for this condition.

Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells bearing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission; OR rising levels of BCR-ABL1 transcript on two consecutive occasions in a patient in complete remission while being treated with PBS-subsidised dasatinib for this condition.

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

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

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

1. a completed authority prescription form; and
2. a completed Acute Lymphoblastic Leukaemia ponatinib PBS Authority Application - Supporting Information Form; and

3. a pathology report demonstrating that the patient had active acute lymphoblastic leukaemia, manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript at the time treatment with ponatinib was initiated. The date of the relevant pathology report(s) need(s) to be provided; or

4. pathology reports documenting rising levels of BCR-ABL1 transcript on two consecutive occasions in a patient in complete remission while being treated with PBS-subsidised dasatinib for this condition. The date of the relevant pathology report(s) need(s) to be provided

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

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

### ponatinib 15 mg tablet, 60

11454W	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1		2	..	5759.65	39.50	Iclusig [TS]

### ponatinib 45 mg tablet, 30

11453T	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1		2	..	6479.09	39.50	Iclusig [TS]

## ■ QUETIAPINE

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

**Note** Authority applications for increased repeats up to a maximum of 5 may be authorised for patients requiring dose optimisation for this condition not adequately provided by other strengths of this drug.

**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.

#### **Authority required (STREAMLINED)**

**7916**

Schizophrenia

#### **Authority required (STREAMLINED)**

**7927**

Acute mania

**Clinical criteria:**

- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be as monotherapy.

#### **Authority required (STREAMLINED)**

**7893**

Bipolar I disorder

**Clinical criteria:**

- The treatment must be maintenance therapy.

### quetiapine 25 mg tablet, 60

8456C	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1		..	..	17.17	18.40	<sup>a</sup> APO-Quetiapine [TX]	<sup>a</sup> Chem mart Quetiapine [CH]
							<sup>a</sup> Delucon 25 [DO]	<sup>a</sup> Kaptan [ER]
							<sup>a</sup> Pharmacor Quetiapine 25 [CR]	<sup>a</sup> Quetia 25 [RW]
							<sup>a</sup> Quetiapine AN[EA]	<sup>a</sup> Quetiapine-DRLA [RZ]
							<sup>a</sup> Quetiapine GH 25 [GQ]	<sup>a</sup> Quetiapine RBX [RA]
							<sup>a</sup> Quetiapine Sandoz [SZ]	<sup>a</sup> Seroquel [AP]
							<sup>a</sup> Syquet [AF]	<sup>a</sup> Terry White Chemists Quetiapine [TW]

# Highly Specialised Drugs Program (Private Hospital)

## ▪ INFLIXIMAB

### Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only. A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time. For paediatric patients with Crohn disease, infliximab is PBS-subsidised for moderate to severe disease while adalimumab is PBS-subsidised for severe disease.

From 1 August 2015, under the PBS, patients commencing on adalimumab will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to infliximab. Patients on infliximab will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine but will need to meet a PCDAI score of greater than or equal to 40 when swapping to adalimumab.

Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine 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 biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine 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 biological medicine therapy after 1 August 2015.

(a) Initial treatment.

Applications for initial treatment should be made where:

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

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 treatment (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

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

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 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy 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 first and subsequent continuing courses of PBS-subsidised biological medicine therapy, 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 should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent Continuing treatment restrictions with that drug 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 therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition. Patients on infliximab may swap to adalimumab within the same treatment cycle provided that their disease severity has progressed to severe disease (i.e. they have a current PCDAI score of 40 or more).

A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice 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 of the PCDAI submitted with the first authority application for a biological medicine. 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.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to assess response to all subsequent treatments.

(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.

Patients must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months immediately prior to the time the PCDAI score is measured.

#### **Authority required**

Moderate to severe Crohn disease

Treatment Phase: Subsequent continuing treatment

#### **Treatment criteria:**

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

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First Continuing treatment restriction; AND
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value; AND
- Patient must have a total PCDAI score of 30 points or less.

#### **Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

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

Patients are only eligible to receive subsequent continuing PBS-subsidised 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.

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**

11450P	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	535.01	<sup>a</sup>	Inflectra [PF]	<sup>a</sup> Renflexis [MK]

## **■ INFLIXIMAB**

### **Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only. A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time. For paediatric patients with Crohn disease, infliximab is PBS-subsidised for moderate to severe disease while adalimumab is PBS-subsidised for severe disease.

From 1 August 2015, under the PBS, patients commencing on adalimumab will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to infliximab. Patients on infliximab will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine but will need to meet a PCDAI score of greater than or equal to 40 when swapping to adalimumab.

---

Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine 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 biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine 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 biological medicine therapy after 1 August 2015.

(a) Initial treatment.

Applications for initial treatment should be made where:

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

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 treatment (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

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

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 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy 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 first and subsequent continuing courses of PBS-subsidised biological medicine therapy, 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 should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent Continuing treatment restrictions with that drug 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 therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition. Patients on infliximab may swap to adalimumab within the same treatment cycle provided that their disease severity has progressed to severe disease (i.e. they have a current PCDAI score of 40 or more).

A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice 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 of the PCDAI submitted with the first authority application for a biological medicine. 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.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to assess response to all subsequent treatments.

(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.

Patients must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months immediately prior to the time the PCDAI score is measured.

**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](http://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 Crohn disease

Treatment Phase: Subsequent continuing treatment

#### **Treatment criteria:**

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

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First Continuing treatment restriction; AND
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value; AND
- Patient must have a total PCDAI score of 30 points or less.

#### **Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

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

(a) a completed authority prescription form; and

(b) a completed Paediatric Crohn Disease PBS Authority Application - Supporting Information Form, which includes the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.

Patients are only eligible to receive subsequent continuing PBS-subsidised 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.

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**

11445J	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	..	535.01	Remicade [JC]

## **■ INFLIXIMAB**

### **Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

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

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time. For paediatric patients with Crohn disease, infliximab is PBS-subsidised for moderate to severe disease while adalimumab is PBS-subsidised for severe disease.

From 1 August 2015, under the PBS, patients commencing on adalimumab will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to infliximab. Patients on infliximab will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine but will need to meet a PCDAI score of greater than or equal to 40 when swapping to adalimumab.

Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine 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 biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine 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 biological medicine therapy after 1 August 2015.

(a) Initial treatment.

Applications for initial treatment should be made where:

- i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 treatment (new patient or Re-commencement of treatment after more than 5 years break in therapy); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 treatment (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 treatment (Change or Re-commencement of treatment after a break in therapy of less than 5 years).

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 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy 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 first and subsequent continuing courses of PBS-subsidised biological medicine therapy, 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 should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent Continuing treatment restrictions with that drug 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 therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition. Patients on infliximab may swap to adalimumab within the same treatment cycle provided that their disease severity has progressed to severe disease (i.e. they have a current PCDAI score of 40 or more).

A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice 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 of the PCDAI submitted with the first authority application for a biological medicine. 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.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to assess response to all subsequent treatments.

(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.

Patients must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months immediately prior to the time the PCDAI score is measured.

---

#### **Authority required**

Moderate to severe Crohn disease

Treatment Phase: Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy

#### **Treatment criteria:**

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

#### **Clinical criteria:**

- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, **AND**
- Patient must have a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 preferably whilst still on treatment.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.  
Application for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Paediatric Crohn Disease PBS Authority Application -Supporting Information Form which includes the following:

(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition which must be no more than one month old at the time of application; and

(ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy] or dates of enteral nutrition.

The PCDAI score should preferably be obtained whilst on conventional treatment but must be obtained within one month of the last conventional treatment dose.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details 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.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

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.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (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 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](http://www.health.gov.au/biosimilars)).

**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](http://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 Crohn disease

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

**Treatment criteria:**

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

**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.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.  
Application for authorisation must be made in writing and must include:

---

(a) a completed authority prescription form; and

(b) a completed Paediatric Crohn Disease PBS Authority Application -Supporting Information Form which includes the following:

(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) Score calculation sheet; and

(ii) details of prior biological medicine treatment including details of date and duration of treatment.

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.

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.

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.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (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](http://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 Crohn disease

Treatment Phase: Balance of supply

#### **Treatment criteria:**

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

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 treatment (New patient or Re commencement of treatment after more than 5 years break in therapy) 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 Initial 2 treatment (Change or Re commencement of treatment after a break in therapy of less than 5 years) 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**

Moderate to severe Crohn disease

Treatment Phase: First continuing treatment

#### **Treatment criteria:**

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

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value; **AND**
- Patient must have a total PCDAI score of 30 points or less.

#### **Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

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

(a) a completed authority prescription form; and

---

(b) a completed Paediatric Crohn Disease PBS Authority Application - Supporting Information Form, which includes the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.

The PCDAI 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 a PCDAI 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 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.

**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](http://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

9612X	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1		..	..	535.01	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [MK]	<sup>a</sup> Remicade [JC]

---

# Highly Specialised Drugs Program (Public Hospital)

## ▪ INFLIXIMAB

### Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only. A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time. For paediatric patients with Crohn disease, infliximab is PBS-subsidised for moderate to severe disease while adalimumab is PBS-subsidised for severe disease.

From 1 August 2015, under the PBS, patients commencing on adalimumab will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to infliximab. Patients on infliximab will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine but will need to meet a PCDAI score of greater than or equal to 40 when swapping to adalimumab. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine 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 biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine 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 biological medicine therapy after 1 August 2015.

(a) Initial treatment.

Applications for initial treatment should be made where:

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

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 treatment (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

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

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 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy 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 first and subsequent continuing courses of PBS-subsidised biological medicine therapy, 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 should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent Continuing treatment restrictions with that drug 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 therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition. Patients on infliximab may swap to adalimumab within the same treatment cycle provided that their disease severity has progressed to severe disease (i.e. they have a current PCDAI score of 40 or more).

A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice 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 of the PCDAI submitted with the first authority application for a biological medicine. 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.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to assess response to all subsequent treatments.

(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.

Patients must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months immediately prior to the time the PCDAI score is measured.

**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](http://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 Crohn disease

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

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

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First Continuing treatment restriction; AND
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value; AND
- Patient must have a total PCDAI score of 30 points or less.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

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

(a) a completed authority prescription form; and

(b) a completed Paediatric Crohn Disease PBS Authority Application - Supporting Information Form, which includes the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.

Patients are only eligible to receive subsequent continuing PBS-subsidised 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.

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

11448M	Max. Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	507.42		Remicade [JC]

### ■ INFLIXIMAB

#### Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only. A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time. For paediatric patients with Crohn disease, infliximab is PBS-subsidised for moderate to severe disease while adalimumab is PBS-subsidised for severe disease.

From 1 August 2015, under the PBS, patients commencing on adalimumab will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to infliximab. Patients on infliximab will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine but will need to meet a PCDAI score of greater than or equal to 40 when swapping to adalimumab.

Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine 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 biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine 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 biological medicine therapy after 1 August 2015.

(a) Initial treatment.

Applications for initial treatment should be made where:

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

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 treatment (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

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

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 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy 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 first and subsequent continuing courses of PBS-subsidised biological medicine therapy, 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 should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent Continuing treatment restrictions with that drug 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 therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition. Patients on infliximab may swap to adalimumab within the same treatment cycle provided that their disease severity has

progressed to severe disease (i.e. they have a current PCDAI score of 40 or more).  
A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice 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 of the PCDAI submitted with the first authority application for a biological medicine. 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.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to assess response to all subsequent treatments.

(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.

Patients must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months immediately prior to the time the PCDAI score is measured.

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

#### **Authority required (STREAMLINED)**

**7931**

Moderate to severe Crohn disease

Treatment Phase: Subsequent continuing treatment

#### **Treatment criteria:**

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

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First Continuing treatment restriction; AND
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value; AND
- Patient must have a total PCDAI score of 30 points or less.

#### **Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

The PCDAI assessment must be no more than 1 month old at the time of prescribing.

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

Patients are only eligible to receive subsequent continuing PBS-subsidised 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**

11449N	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4		2	..	*2029.68 <sup>a</sup>	Inflectra [PF]	<sup>a</sup> Renflexis [MK]

## **■ INFLIXIMAB**

### **Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only. A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time. For paediatric patients with Crohn disease, infliximab is PBS-subsidised for moderate to severe disease while adalimumab is PBS-subsidised for severe disease.

From 1 August 2015, under the PBS, patients commencing on adalimumab will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to infliximab. Patients on infliximab will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine but will need to meet a PCDAI score of greater than or equal to 40 when swapping to adalimumab.

Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine 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 biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine 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 biological medicine therapy after 1 August 2015.

(a) Initial treatment.

Applications for initial treatment should be made where:

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

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 treatment (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

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

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 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy 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 first and subsequent continuing courses of PBS-subsidised biological medicine therapy, 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 should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent Continuing treatment restrictions with that drug 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 therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition. Patients on infliximab may swap to adalimumab within the same treatment cycle provided that their disease severity has progressed to severe disease (i.e. they have a current PCDAI score of 40 or more).

A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice 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 of the PCDAI submitted with the first authority application for a biological medicine. 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.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to assess response to all subsequent treatments.

(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.

Patients must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months immediately prior to the time the PCDAI score is measured.

---

#### **Authority required**

Moderate to severe Crohn disease

Treatment Phase: Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy

**Treatment criteria:**

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

**Clinical criteria:**

- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, **AND**
- Patient must have a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 preferably whilst still on treatment.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

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

(a) a completed authority prescription form; and

(b) a completed Paediatric Crohn Disease PBS Authority Application -Supporting Information Form which includes the following:

- (i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition which must be no more than one month old at the time of application; and
- (ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy] or dates of enteral nutrition.

The PCDAI score should preferably be obtained whilst on conventional treatment but must be obtained within one month of the last conventional treatment dose.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details 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.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

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.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (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 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](http://www.health.gov.au/biosimilars)).

**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](http://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 Crohn disease

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

**Treatment criteria:**

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

**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.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

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

(a) a completed authority prescription form; and

(b) a completed Paediatric Crohn Disease PBS Authority Application -Supporting Information Form which includes the following:

(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) Score calculation sheet; and

(ii) details of prior biological medicine treatment including details of date and duration of treatment.

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.

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.

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.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (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](http://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 Crohn disease

Treatment Phase: Balance of supply

**Treatment criteria:**

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

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 treatment (New patient or Re-commencement of treatment after more than 5 years break in therapy) 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 Initial 2 treatment (Change or Re-commencement of treatment after a break in therapy of less than 5 years) 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**

Moderate to severe Crohn disease

Treatment Phase: First continuing treatment

**Treatment criteria:**

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

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value; AND
- Patient must have a total PCDAI score of 30 points or less.

---

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

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

(a) a completed authority prescription form; and

(b) a completed Paediatric Crohn Disease PBS Authority Application - Supporting Information Form, which includes the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.

The PCDAI 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 a PCDAI 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 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.

**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](http://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**

5755X	Max. Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1		..	..	507.42	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [MK]	<sup>a</sup> Remicade [JC]

---